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ROYAL COMMISSION OF INQUIRY INTO CERTAIN
DEATHS AT THE HOSPITAL FOR SICK CHILDREN AND
RELATED MATTERS.

Re-Ex. Etc

Hearing held
8th floor
180 Dundas Street West
Toronto, Ontario

Ellis

The Honourable Mr. Justice S.G.M. Grange

P.S.A. Lamek, Q.C.

E.A. Cronk

Thomas Millar

Commissioner

Counsel

Associate Counsel

Administrator

Mr. Ch. Etc

Transcript of evidence
for

October 12, 1983

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DEATHS AT THE HOSPITAL FOR SICK CHILDREN
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Hearing held on the 8th Floor,
180 Dundas Street West, Toronto,
Ontario, on Wednesday, the 12th
day of October, 1983.

- - - - -

THE HONOURABLE MR. JUSTICE S.G.M. GRANGE - Commissioner
THOMAS MILLAR - Administrator
MURRAY R. ELLIOT - Registrar

- - - - -

APPEARANCES:

| | |
|----------------------|--------------------------------|
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| E. CRONK) | |
| T.C. MARSHALL, Q.C.) | Counsel for the Attorney- |
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| L. CEECHETTO) | of Ontario (Crown Attorneys |
| | and Coroner's Office) |
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| | Children |
| B. SYMES | Counsel for the Registered |
| | Nurses' Association of Ontario |
| | and 35 Registered Nurses at |
| | The Hospital for Sick Children |

(Cont'd)



APPEARANCES: (Continued)

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| 2 | | Nurse |
| 3 | E. FORSTER | Counsel for Phyllis Trayner - |
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| 12 | | Mr. & Mrs. Lutes (parents of |
| 13 | | deceased children) |
| 14 | F.J. SHANAHAN | Counsel for Mr. & Mrs. Dominic |
| 15 | | Lombardo (parents of deceased |
| 16 | | child Stephanie Lombardo); and |
| 17 | | Heather Dawson (mother of |
| 18 | | deceased child Amber Dawson) |
| 19 | W.W. TOBIAS | Counsel for Mr. & Mrs. Hines |
| 20 | | (parents of deceased child |
| 21 | | Jordan Hines) |
| 22 | J. SHINEHOFT | Counsel for Lorie Pacsai and |
| 23 | | Kevin Garnet (parents of |
| 24 | | deceased child Kevin Pacsai) |
| 25 | | |



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/DM/ak

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2

---Upon commencing at 10:00 a.m.

3

THE COMMISSIONER: Yes, Miss Cronk.

4

DR. ERNEST CUTZ, Resumed

5

RE-DIRECT EXAMINATION BY MS. CRONK:

6

Q. Good morning, Dr. Cutz.

7

A. Good morning.

8

Q. Dr. Cutz, do you recall having

9

a discussion with Mr. Scott last Tuesday regarding
the samples for digoxin assay that were taken from

10

the body of Janice Estrella?

11

A. Yes, I do.

12

Q. I would like to be clear,

13

Doctor, as to what your evidence in respect of that
matter is.

14

15

First, as I understand it, you had
absolutely no involvement in the actual performance
of the autopsy on Janice Estrella, do I have that
correctly?

16

17

18

A. That is correct, yes.

19

Q. You were not there when the

20

blood samples were taken which were later used for
digoxin assay, and because you were not there as I
understand it you did not observe how and in what
manner the samples were actually taken?

21


22

23

A. No, I didn't.

24

25



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Q. And similarly, Doctor, because you were not there, you did not have an opportunity to observe what the condition of the body was at the time those samples were taken; do I have that correctly?

A. Yes.

Q. And you had no involvement as I understand it in the preparation of the final autopsy report which was later prepared concerning the autopsy on Janice Estrella?

A. Yes, that is correct.

Q. Did you - and because you didn't have any involvement at that stage I take it then that you did not then have the opportunity to discuss with Dr. Taylor the manner in which he had personally obtained those samples from the body of Janice Estrella?

A. No, I did not.

Q. Did you subsequently, after the autopsy had been performed and the final autopsy report prepared, have an opportunity prior to the end of March, 1981 to discuss with Dr. Taylor the manner in which he had obtained those samples and the condition of the body at the time that he obtained them?



1

2

A. No, I did not.

3

Q. I take it then, Doctor, that

4

you do not know for a fact what was or was not present

5

in the pelvic cavity of Janice Estrella at the time

6

a blood was taken from that source for digoxin assay;

7

is that correct?

8

A. Yes.

9

Q. And Doctor, as I understood

10

your previous evidence, you told us that prior to the

11

case of Kevin Pacsai, you had never taken a sample,

12

a blood sample for a postmortem digoxin assay; is

that correct?

13

A. That is correct.

14

Q. Pacsai was your first

15

experience in that regard?

16

A. Yes.

17

Q. And when it came to the case

18

of Kevin Pacsai, as I understood your evidence, you

19

did not milk a leg vein to obtain the sample, but

20

rather you used a syringe to aspirate or to draw

21

the blood directly from the inferior vena cava; is

that correct?

22

A. That's correct.

23

Q. And similarly when we come to

24

the case of Allana Miller, and we know you had

25



1
2 involvement on that autopsy, you did not I take it
3 observe Dr. Taylor draw a blood specimen by milking
4 a leg vein from that child?

5 A. No, we did not.

6 Q. That sample as well was drawn
7 directly from the inferior vena cava by the use of
8 a syringe and a needle you have told us.

9 A. That is correct.

10 Q. And when we come to the case
11 of Justin Cook, once again I take it you did not
12 observe Dr. Taylor milking a leg vein in respect of
13 that child to obtain a blood specimen for digoxin
14 assay?

15 A. That is correct.

16 Q. Have you in fact, Doctor, ever
17 observed Dr. Taylor milking a leg vein for the
18 purposes of obtaining a blood specimen for a digoxin
19 assay?

20 A. No, I did not.

21 Q. Have you yourself ever had
22 occasion to do so?

23 A. No, I did not.

24 Q. Doctor, as I understood your
25 evidence with respect to your discussion with
Mr. Scott, you told him that you were present at



1
2 least in part for the evidence of Dr. Taylor on his
3 last day here; do you recall that?

4 A. Yes, I was.

5 Q. You would have heard then I
6 take it, you would have heard Dr. Taylor describe the
7 precautions which he took prior to drawing that leg
8 vein sample from the body of Janice Estrella?

9 A. No, I don't believe I was
10 here when he discussed the manner by which he
11 obtained the sample, I think it was some other aspect.

12 Q. All right. Do you recall him
13 talking about, in the sense of precautions that he
14 took, talking about cleaning and drawing the surround-
15 ing tissues near the cut by the leg vein; do you
16 recall that?

17 A. I recall hearing it, but I am
18 not sure whether I heard it here.

19 Q. Do you have any recollection of
20 hearing Dr. Taylor here in these proceedings indicat-
21 ing that he allowed a few drops of blood to flow out
22 of the vein before he then used a syringe to aspirate
23 blood back into the syringe to take the sample?

24 A. Yes, I heard about that.

25 Q. Did you also hear Dr. Taylor
here in this court room say that he had given



1
2
3 attention to the site from which he could draw a
4 clean sample, and he felt that the leg vein site
5 itself was the only then available site from which
6 he could obtain a clean specimen of blood, did you
hear him say that as well?

7 A. Yes.

8 Q. You heard him I take it say
9 that he used a syringe and not a collector receptacle
10 of some other kind to obtain that blood specimen;
did you hear him say that?

11 A. He did, yes.

12 Q. Doctor, you said, as I under-
13 stood, that in order for Dr. Taylor to obtain blood
14 from the leg vein, these were your words, he had
15 to exert quite a lot of pressure on the leg tissues,
16 perhaps introducing some more edema fluid or fluid
17 from the muscle, possibly causing some contamination;
do you recall giving that evidence, Doctor?

18 A. I can't recall it exactly,
19 it might have come up.

20 Q. To assist you and the
21 Commissioner that evidence is found in Volume 44,
22 page 9018 and I will ask you to accept for the
23 moment that that is the language that you used.

24 Doctor, I am curious as to the basis
25



1
2 upon which you felt that Dr. Taylor had to exert
3 quite a lot of pressure on the leg vein to draw
4 that sample. I take it that Dr. Taylor didn't tell
5 you that; am I correct?

6 A. No.

7 Q. And I take it you didn't hear
8 Dr. Taylor say that in this court room?

9 A. I heard Dr. Mancer at some
10 other point describing it. I am not sure whether
11 I heard Dr. Taylor, at what stage I came in I can't
12 recall.

13 Q. Do you have any recollection
14 of hearing Dr. Taylor, the person who drew the
15 sample, describe the way he drew the sample by
16 saying he had to exert a great deal of pressure on
17 those muscles in the leg to draw the blood, did you
18 hear Dr. Taylor say that?

19 A. I heard the discussion but I
20 am not certain it was from Dr. Taylor.

21 Q. What I am suggesting to you,
22 Doctor, ---

23 THE COMMISSIONER: Just a moment,
24 Miss Cronk.

25 MR. ROLAND: Mr. Commissioner, as
I recall the evidence, and I may be wrong in this,



1
2 it is my recollection is it wasn't Dr. Taylor that
3 milked the leg vein, with his hand on the leg, it
4 was Dr. Gillan who was with him and Dr. Taylor was
5 drawing the sample. So to put to the witness how
6 much pressure Dr. Taylor exerted is not ---

7 THE COMMISSIONER: I remember
8 Dr. Gillan held the leg up, whether he also applied
9 the pressure or not I don't know.

10 MR. ROLAND: I think that was the
11 evidence.

12 MS. CRONK: It was only in light -
13 that may indeed be correct. Certainly the evidence
14 to date is that those two doctors in concert obtained
15 that sample. I had understood Dr. Cutz to say that
16 Dr. Taylor had applied a considerable amount of
17 pressure to do so. I am simply exploring the basis
18 of the Doctor's information in making that statement.

19 Q. Doctor, I am suggesting to you
20 that unless you had a discussion either with
21 Dr. Taylor or Dr. Gillan at which time either
22 explained to you the exact method used by them to
23 draw that sample, that your suggestion that they did
24 not easily obtain the sample but rather had to
25 exert a great deal of pressure, or indeed any
pressure at all, is really an assumption on your part?



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A. Yes, it is an assumption, I assume that the question which was put to me was to get my opinion on the matter rather than comment on the facts, which obviously I have not been present.

Q. I understand, Doctor.

A. Yes.

Q. And because you assumed that that was - that the sample was not easily obtained and the pressure had to be exerted to obtain it, it was on that basis, on that basis of that assumption that you said that perhaps some edema fluid or fluid from the muscles might have been introduced?

A. That's correct.

Q. And as we indicated because you were not there you do not in fact know whether in fact edema fluid or muscle tissue was introduced into the sample?

A. That is correct.

Q. Doctor, with respect to the reading itself that was obtained on the leg vein sample. You were asked during the course of cross-examination by Mr. Scott about the level itself. You were asked as I understood it what you would have done to pursue that level further, assuming it was not possible to further dilute the sample. We are



1
2 talking now about the leg vein sample that resulted
3 in a reading of greater than 4.7 nanograms?

4 A. Yes.

5 Q. Do you recall Mr. Scott asking
6 you that question?

7 A. Yes, I do.

8 Q. And in that regard, as I
9 understood your evidence, Doctor, you indicated a
10 number of things. Firstly you indicated that if you
11 were unable to explain the level you might wish to
12 speak to the clinicians on the assumption that they
13 would know more about digoxin levels than perhaps
14 the pathologists involved would, do I have that
15 correctly?

16 A. Yes.

17 Q. Doctor, it is my understanding
18 that when a level of greater than 4.7 nanograms is
19 recorded by the Biochemistry Department at the
20 Hospital in respect of the digoxin assay, that means
21 that the digoxin concentration in the sample is
22 greater than the maximum which can be measured with-
23 out further dilution on the assay or the RIA test;
24 and to know the exact level further dilution is
25 required and the sample must be re-assayed. Does
that accord with your understanding?



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A. Yes.

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Q. Yes, Doctor.

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Q. In those circumstances, Doctor, would you agree with me that if the sample could not be diluted further, and the first and only reading was simply off the maximum that the assay test was able to produce, we cannot with certainty know what the level in fact was; would you agree with that?

A. Yes, you cannot be absolutely certain but in other cases it may give some other initial readings as I remember in the Pacsai case, the pre-mortem level was even greater than 10.

A. And there are some other examples where it cannot be diluted. So I am not sure, you know, how much importance one can put to the first reading and what is expected once you dilute it.

Q. Doctor, I'm not asking you at the moment for the significance which you place or attach to that level.

A. Yes.

Q. My question, or my suggestion to you merely was that without further dilution and without further assay, it is not possible to say what that level in fact was, how much higher it was



1

2

than 4.7; would you agree with that, Doctor?

3

A. Yes, I would.

4

Q. And you have drawn my attention

5

to the Pacsai case?

6

A. Yes.

7

Q. Let's talk about that for a

8

moment if we may. Doctor, we know of course that

9

you performed that autopsy and you have familiarity

10

both with the antemortem level and with the postmortem
level that was recorded for Kevin Pacsai, correct?

11

A. Yes, this is later on.

12

Q. Yes, later on, right.

13

A. Yes.

14

Q. Doctor, were you aware in

15

respect of Kevin Pacsai 26 nanograms postmortem level

16

that Dr. Ellis' Digoxin books maintained in the

17

biochemistry laboratory suggest that the first time

18

that sample was assayed a result of greater than 4.8
was obtained?

19

A. No, I am not familiar with that,

20

no.

21

Q. Were you aware, Doctor, that

22

the entries in those books suggest that after it

23

was assayed first it had to be diluted; it was

24

re-assayed and a level of 24 nanograms was achieved;

25



1

2

were you aware of that?

3

A. No, I am not, no.

4

Q. Were you aware, Doctor, that

5

it was diluted and re-assayed again, at least that

6

would appear to be the case from the Digoxin books;

7

and we will hear from Dr. Ellis. On that further

8

dilution, on further assay it resulted in a level

9

of 25.5 nanograms. Then it was diluted again and

10

re-assayed again and that is when the level of 26

nanograms was achieved?

11

A. No, I was only told about the

12

final reading as being 26.

13

Q. I understand, Doctor.

14

Similarly in the case of Allana Miller we know that

15

you supervised that autopsy and Dr. Taylor drew

16

samples that were ultimately tested post mortem for

17

digoxin assay; were you aware in the case of Allana

18

Miller the entries in Dr. Ellis' Digoxin Assay books

19

suggests that on the first assay run the postmortem

20

sample resulted merely in a level of greater than 5

nanograms?

21

A. No, I did not know.

22

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Q. All right. Were you aware, Doctor, that several dilutions, in fact three, appear to have taken place before a level of 78 nanograms was achieved on that sample of Allana Miller?

A. No, I didn't know.

Q. All right. Doctor, if that be so, if in the case of Kevin Pacsai the first reading was merely greater 4.8 and in fact the ultimate fixed reading was 26 and if in the case of Allana Miller the first reading was greater than 5 and the ultimate fixed reading was 78, with those two cases in mind, I take it we can agree that we cannot reasonably assume that a greater than 4.7 level in the case of Janice Estrella would result in a fixed level of less than 10 as you suggested. We can't reasonably assume that, can we, Doctor?

A. Yes. No, I based that comment on the fact that, you know, we had these various dilutions showing different levels at the final reading but, you know, unless you have the diluted final reading you cannot be certain what the actual level is.

Q. Thank you, Doctor. One other point with respect to the Estrella sample. You will recall that I suggested to you that Mr. Scott



1
2 had inquired of you what you would have done if you
3 had obtained that level and you wished to investigate
4 the matter further and I suggested to you that your
5 response was that you said that if you couldn't explain
6 it, you could perhaps talk to the clinicians on the
7 assumption that they would probably be more knowledgeable
8 about the levels of digoxin than the involved
9 pathologist was. Do you recall that evidence?

10 A. Yes.

11 Q. All right. We know that your
12 own experience, your own first experience with a
13 postmortem digoxin level was in the case of Kevin
14 Pacsai and in that case, as I understood your evidence,
15 when you were informed of the level of 26 nanograms
16 you discussed the matter with Dr. Costigan on March
17 18th, is that correct?

18 A. Yes, I was told by Dr.
19 Costigan.

20 Q. All right. And in the course
21 of that discussion you reviewed with him the level?

22 A. No. I had only a brief
23 discussion where he told me what the finding was but
24 I can't recall as to what detail we went into as to
25 the interpretation.

Q. All right. And further on



1

2

March 18th you discussed the matter of that level with Dr. Fowler, as I understood your evidence?

3

3

4

A. Well, this again was just a brief encounter and we have not concentrated on a discussion about the level itself. But as I understood the purpose of Dr. Fowler's visit was to obtain and review the chart which was in my possession at the time.

5

6

7

8

9

Q. All right. And you saw Dr. Fowler?

10

11

A. Yes.

12

Q. And provided the chart to him on the 18th?

13

A. That's right.

14

15

Q. And that was because of the Pacsai level that had been obtained and you thought, you knew that that was why he was looking at the chart?

16

17

A. That is correct, yes.

18

19

Q. All right. And also on March 18th, you did discuss it with Dr. Ellis, you have told us?

20

21

A. That is correct.

22

23

Q. And that conversation was a more detailed one than the other two that you have

24

25



1

4

2

just described?

3

A. Yes. That was more - I think

4

Dr. Ellis came to see me to enquire about that sample.

5

Q. All right. And you had a

6

discussion with him?

7

A. Yes.

8

Q. As to the level?

9

A. Yes.

10

Q. And as I recall with respect

11

to whether or not any tissue samples were available
and you discussed how that level might have been
achieved?

12

A. That's correct, yes.

13

Q. Do I have that correctly?

14

A. Yes.

15

Q. All right. And then as I

16

understood it, after discussing the matter with those
three individuals on March 18th you sought out Dr.

17

Mancer on March 20th for the specific purpose of
obtaining his input with respect to that level?

18

19

A. Yes.

20

Q. Am I correct?

21

A. That's correct, yes.

22

Q. So that in respect of the

23

Kevin Pacsai level about which you had been informed

24

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it was raised in discussions that you held with
Dr. Fowler, Dr. Costigan, Dr. Ellis and Dr. Mancer
either on the 18th of March or on the 20th of March?

A. Could you rephrase it, please.

Q. In respect of that Pacsai
level, the 26 nanograms.

A. Yes.

Q. That was a matter of discussion
between yourself and Dr. Costigan, Dr. Fowler, Dr.
Ellis and Dr. Mancer on March 18th and on March 20th.

A. Yes.

Q. Is that correct?

A. Yes, yes.

Q. All right. Doctor, as I
understood your evidence with Mr. Scott you suggested
that you had also discussed the matter with Dr.
MacLeod of the Pharmacology Department at the Hospital.
Do I have that correctly?

A. Yes. I discussed it, I can't
recollect the exact time but we certainly discussed
it either after the 25th, probably after the 25th
of March.

Q. That was my next question,
Doctor, when you discussed it with Dr. MacLeod?

A. I can't recall that that would



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have been prior to the 26th of March.

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Q. All right. And I take it then at that time it was discussed by Dr. MacLeod and yourself in the context of the events that had taken place over the weekend of March 21st?

A. That is correct, yes.

Q. All right. Doctor, I would like to draw your attention now to Exhibit 198. Mr. Registrar, perhaps if you could show the Doctor a copy of that.

Doctor, as I understood your evidence with respect to this exhibit, specifically the column entitled Cause of Death.

A. Yes.

Q. You told me, as I understood it, that the information contained in those columns was based on the findings detailed in the autopsy reports of the individual cases. Do I have that correctly?

A. Yes, that is correct.

Q. All right. And you also told me, as I understood it, that the autopsy reports included the microscopic examination results. Do I have that correctly?

A. Yes.



1
2 Q. All right. And as I understood
3 it, in cross-examination and discussion with Mr.
4 Scott you indicated that the actual autopsy reports,
5 including the pathological discussion sections of
6 those reports were prepared between 11:00 a.m. on
7 Tuesday March 24th and 10:00 a.m. on Wednesday, March
8 25th. Do I have that correctly?

9 A. Yes.

10 Q. 1981?

11 A. Yes.

12 Q. All right. In the case of
13 Kevin Pacsai your attention was drawn by Mr. Scott
14 to the document that is entitled Preliminary Autopsy
15 Report?

16 A. Yes.

17 Q. Do you recall that?

18 A. Yes.

19 Q. And your evidence in that
20 regard with that report was really nothing more than
21 your personal notes. Do I have that correctly?

22 A. Yes.

23 Q. All right. Doctor, in respect
24 of that document, I take it and you have told us
25 previously that it is not the normal practice in a
coroner's case for a preliminary autopsy report



8

1

2

so-called to be prepared at the Hospital. Is that correct?

3

4

A. Well, it would be prepared but it would not be distributed. In other words, it would not leave my office.

5

6

7

Q. Is it then, Doctor, in a coroner's case your normal practice to prepare a preliminary autopsy report as well as the report of the postmortem examination that goes to the coroner?

8

9

10

A. Yes.

11

12

Q. All right. And for what purpose do you prepare those preliminary autopsy reports in coroner's cases?

13

14

A. Well, it is for my own personal use when the final report is signed out so I can refresh my memory two months later what the problems were and put it into the context, you know, what the findings were then and what they are after all these things are completed. So, it is for my personal use and it may also be used by the neuropathologists when they examine the brain so they know what the case is about.

15

16

17

18

19

20

21

Q. Someone such as Dr. Becker?

22

A. Such as Dr. Becker, yes.

23

Q. All right. And is that report,

24

25



1
2 the preliminary autopsy report that you would prepare
3 maintained in the Pathology Department?

4 A. That is correct, yes.

5 Q. All right. And is that copy
6 that is maintained in the Pathology Department then
7 available for other members of the Pathology Department
8 to review should they wish to do so?

9 A. Yes.

10 Q. All right. And was that the
11 case with respect to this preliminary autopsy report?

12 A. Well, it was for basically the
13 same purpose but it would not leave the Department.

14 Q. All right. I take it then,
15 Doctor, that because it was prepared for your own
16 future reference at the time of signing out the
17 final autopsy report and as well for the purposes
18 of being available to other colleagues such as Dr.
19 Becker and other members of the Pathology Department
20 that that is why it is typed up in the form in which
21 we see this one and your signature appears formally
22 on the bottom of the report?

23 A. That is correct, yes.

24 Q. All right. If it was simply
25 your own personal notes I take it that that degree
of formality might not be required?



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A. Well, it is not really a degree of formality. The signature means that I have prepared it and I have seen it.

Q. All right.

A. Since it's typed.

Q. All right. And in the normal case, as I understand it, Doctor, as you have explained it, there would be an interval of time elapsed between the date of your signing the preliminary autopsy report and the date of preparing and finalizing the final autopsy report. Do I have that correct?

A. Yes.

Q. So that the preliminary autopsy report, even in a coroner's case, serves as a useful tool for you to refresh your memory when it comes time to complete and finalize the final autopsy report?

A. That is correct, yes.

Q. All right. Now, Doctor, as I understood your evidence you were asked when, in the case of Kevin Pacsai, the preliminary autopsy report was prepared and I had understood your evidence to be that you had thought that it was at the same time as the final autopsy report, that is, in the latter



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part of Tuesday, March 24th or the early part of
Wednesday, March 25th. Is that your evidence in that
regard?

A. Yes.

Q. All right. Do you have any
recollection one way or another, Doctor, as to when
this preliminary autopsy report was prepared?

A. I do not know the exact date
or I can't recall exactly but I could not have made
it before the 18th because I didn't know the results.

Q. All right.

A. And after the 18th the things
went fast, I had other things to worry about. So,
I'm almost sure that I could not make, did not make
that report before Monday.

Q. All right. My only curiosity
arises - Monday, March 23rd?

A. Yes.

Q. All right. My only curiosity
arises with respect to the date, Doctor, for this
reason. As I have understood your evidence, Dr.
Mancer and yourself were hard pressed, under con-
siderable time pressures to complete all of the final
autopsy reports that you in fact had been requested
to complete the evening of March 24th and the afternoon



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of March 24th and the morning of March 25th?

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A. Yes.

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Q. Do I have that correct?

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A. Yes.

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Q. And given those time

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constraints and given that you had 10 final autopsy
reports to prepare, I found it curious that you would

8

also take it upon yourself at that stage to prepare

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a preliminary autopsy report for Kevin Pacsai instead

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of going directly to the final. My suggestion to you

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is, that given your evidence with respect to the

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climate of those two days when you were preparing

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those reports, that it is likely that this preliminary

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autopsy report was prepared prior to March 24th?

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A. No. I can maybe explain it

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on the fact that when actually the so-called pre-

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liminary report was prepared it has several notes

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on it saying that brain has not been examined I

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believe and that the conduction system was not

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examined.

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And at the time this report was prepared the heart was already seized, or the heart tissue that we had was already seized, so that because these other studies were not completed yet and since this report was in this circumstance was more intended to give information for the investigation --

Q. Did that apply, Doctor, both to the preliminary autopsy report and the final one?

A. No, the final report was written - it would be written on April 20th or so.

Q. Are you saying that --

A. It was prepared the same time the coroner's report was prepared, and copy of the final report on the Hospital stationery would just go into the books within the department.

Q. All right. Doctor, I would like to be clear on this.

A. Yes.

Q. I am showing you a copy of the final autopsy report which is Exhibit 106A.

A. Yes.

Q. I am showing you as well a copy of the preliminary autopsy report.

A. Yes.

Q. Is it your evidence that the



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final autopsy report was not prepared on March 24th and March 25th and was delivered and was available to the police but rather only the preliminary autopsy report?

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A. Yes.

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Q. Thank you.

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So the report then which came into the possession of the Metropolitan Toronto Police as a result of your efforts and those of Dr. Mancer in those two days is the preliminary autopsy report?

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A. That is correct.

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Q. And I take it we can agree, Doctor, that the conclusion reached in that report is the same as the conclusion reached by you in the final report which you ultimately signed, and that is that the immediate cause of death was digitalis toxicity?

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A. Yes, that is correct.

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Q. Am I correct in that regard?

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Right.

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I take it we can agree, Doctor, that whether or not the Metropolitan Toronto Police had become involved at the Hospital, their involvement one way or another doesn't affect the fact that a postmortem digoxin level of 26 nanograms was reported in this case?



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A. That is correct.

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Q. All right. You told Mr. Scott

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as I understood it that that level of 26 nanograms was

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a level that you could not explain on the basis of

6

the pathological and clinical findings in this case?

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A. That is correct, yes.

8

Q. Do I have that correctly, Doctor?

9

A. Yes.

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Q. I suggest to you, Doctor, in

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those circumstances whatever else happened that level

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could not be ignored by you and indeed it wasn't, and

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it was on the basis of that level that you concluded

this child died of digitalis toxicity?

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A. Yes.

15

Q. All right. And whether or not

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the police were there on March 23rd or April 23rd or

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May 23rd that was a level that you as a pathologist

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could not have ignored given your concerns about it,

and it would have led you to the conclusion that

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this child died of digitalis toxicity?

20

A. Yes.

21

Q. All right.

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Doctor, you were asked as well by Mr.

23

Scott why the post mortem level had been ordered for

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digoxin in respect to Kevin Pacsai, and as I understood

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your evidence yesterday it was suggested to you by
Mr. Scott, and you agreed, that the medical chart
had directed your attention to digoxin in this case.
Do you recall that?

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A. Yes.

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Q. And Mr. Scott suggested to you
that it was Dr. Costigan's two notes on the chart
which led you to order that level?

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A. Yes.

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Q. Do you recall that?

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A. Yes.

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Q. All right. Doctor, you may
recall during our discussion in chief that I as well
asked you why you had ordered that postmortem digoxin
level, and I had understood your answer to be perhaps
a little different than the one that was offered
yesterday and I would like simply to refresh your
memory.

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It appears at Volume 42, page 8543
I asked you who had ordered the digoxin level in the
Pacsai case, and you told me that you had, and I then
asked you this question:

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"All right. Can you tell me, Doctor,
why in this case you did that?

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"A. Well, as I mentioned, I try to do

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And your answer was:

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"a thorough autopsy covering the various possibilities and this appeared as one possibility. So that was the only reason to actually do it.

"Q Prior to this case, Doctor, had you ever had occasion during any other autopsy that you conducted at the Hospital to order a postmortem digoxin level on a patient?

"A. No, I had not ordered it but I also didn't have a case like Pacsai.

"Q Well, what was there about the Pacsai case that led you to order a postmortem digoxin level?"

"Well, the clinical history of these various conduction disturbances, arrhythmias, problems with potassium are really minor or almost no anatomical findings.

"Q Was there anything else in the clinical history of the child, Doctor, that influenced you to order a post-mortem digoxin level?

"A. No, not really, nothing. That's based solely on clinical information."



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I take it, Doctor, then you were motivated to order a postmortem digoxin level in the case of Kevin Pacsai first upon the basis of your review of the medical chart and your recognition that Dr. Costigan had twice reported a query about digoxin toxicity?

A. Yes.

Q. These two notes were one factor; is that correct?

A. Well, maybe this discrepancy or which appears to be a discrepancy would be due to a lapse of memory.

Q. Well, Doctor, my only point at this stage is this: the things that you took into account --

A. Yes.

Q. -- were several.

A. Yes.

Q. First the two notes written by Dr. Costigan. Do I have that correctly?

A. Yes.

Q. And he had directly queried digoxin toxicity.

A. Yes.

Q. And you read that not once but



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twice in the chart?

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A. Yes.

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Q. Secondly you noticed on your

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review of the chart because you personally reviewed

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in this case the arrhythmias that had been experienced
by the child?

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A. That is correct, yes.

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Q. And you noticed as well the

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recording of conduction disturbances that had been

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noted during life and you noticed that on the basis

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of your review of the record?

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A. Yes.

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Q. And as well, Doctor, I take it

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because you suggested you never before had a case like

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Pacsai that your conversation with Dr. Fowler when

16

he suggested to you that it was a puzzling case, that

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in itself set this case slightly apart from others

that you had dealt with in the past?

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A. Yes. This would be before I

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actually had an opportunity to see the chart when I

20

was talking to Dr. Fowler, so I didn't really know

the details of the case.

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Q. Well, it was on the basis of

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all of those factors and your discussion with Dr.

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Fowler that you proceeded to order a postmortem digoxin

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level?

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A. Well, not really. I think to be fair, you know, I considered these various possibilities, and as far as digoxin toxicity is concerned I was not expecting to get a sky-high level. What I was expecting perhaps would be maybe slightly higher level within the therapeutic range.

Q. I understand your evidence, Doctor, as to what you were expecting. What I am asking you to direct your mind to --

A. Yes.

Q. -- is what factor or factors motivated you in the first instance to order the level, and I had thought your evidence to be that it was a number of things that you noted in the medical chart.

A. Yes.

Q. That being the arrhythmias, the conduction disturbances, the queries by Dr. Costigan regarding digoxin toxicity, and as well that you had never had a case like Kevin Pacsai before? That is what you told me previously.

A. That is correct, yes.

Q. And is it your evidence today that those were the factors that you took into account in ordering this digoxin level?

A. That is correct, yes.



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Q. Do you recall, as well, Doctor, one final point in the course of your discussion with Mr. Scott, telling Mr. Scott that there was a well known and important interaction between digoxin and potassium?

A. Yes.

Q. Do you recall that?

A. Yes.

MS. CRONK: Mr. Commissioner, this evidence appears at Volume 44, page 9045.

That interaction as I understood you to explain it, Dr. Cutz, in your view is that if you have a low potassium level then there is a heightened adverse effect of digoxin on the heart?

A. Yes.

Q. Do I have that correctly?

A. Yes.

Q. And I know, Doctor, from your prior evidence that you are familiar with the ante-mortem and postmortem potassium levels for Kevin Pacsai?

A. Yes.

Q. Indeed with respect to the ante-mortem levels your attention was specifically drawn to those by Dr. Tepperman in the coroner's warrant?

A. That is correct, yes.



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Q. And you know then, Doctor, on the child's arrival at The Hospital for Sick Children he had a potassium level of 3.9. Do you recall that?

A. Yes, I believe so, yes.

Q. And you recall as well that during the morning on March 12th, the day that he died, he had a potassium level of 9, and then later in the day when another sample was taken at 7:20 he had a potassium level of 7.7. Do you recall that?

A. I understood the level 9 was only hemolyzed sample which would be inadequate or would not be a reliable sample so for that reason it was repeated.

Q. Was the 7.7 level --

A. Yes.

Q. -- an unhemolyzed sample?

A. No, that was a proper sample.

Q. All right. But those three samples were recorded during life?

A. Yes.

Q. Originally the 3.9 on transfer and then a 9 on the day that he died and a 7.7 also on the day he died?

A. That is correct.

Q. And you would have no queries



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with respect to the final level of 7.7 on the basis
that it was not a hemolyzed sample? That is not a
concern with respect to that sample?

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A. Well, it is a high level but --

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Q. But it wasn't a hemolyzed sample?

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A. That is right, no.

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Q. And the postmortem level you
previously told us was 11.6?

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A. Correct.

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Q. I take it we can agree, Doctor,
that Kevin Pacsai's potassium levels during life on
the basis of those numbers were elevated by the time
that he died well over normal? 9 and 7.7.

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A. Yes.

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Q. All right. So that the inter-
action between potassium and digoxin which you
described to Mr. Scott would not I take it in your
view account for a digoxin level of greater than 10
during life and 26 after death?

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A. No.

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Q. All right, thank you, Doctor.

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And, Doctor, you will recall that
Mr. Scott drew to your attention a number of causes of
death that were described as such by Dr. Rowe during
the course of his evidence and your opinion was sought

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with respect to each as to whether or not you as a pathologist would expect to see any pathological indicators (my word) or findings suggestive of that cause of death if you performed the autopsy.

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Do you remember that exchange yesterday?

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A. Yes, I do.

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Q. And your attention first, and I don't intend to go through all of them, Doctor, but I will suggest a number of them to you - your attention first was drawn by Mr. Scott to pump failure, what Dr. Rowe had described as heart failure being a cause of death. Do you recall that?

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A. Yes.

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Q. And your evidence in that regard as I understood it, Doctor, this appears in yesterday's transcript at page 378. Mr. Scott asked you, Doctor, whether there were cases where you would not expect to see evidence of pump failure at autopsy and your answer was:

"A. Yes, in instantaneous type of death you would not see evidence of pump failure.

Q. So if you had a sudden death which was attributed to a pump failure where there was an anatomical defect, do I understand that you might not therefore see at autopsy any evidence pointing to that cause?

A. That is correct.

Q. But nonetheless, you could not exclude the cause?

A. No, yes."

Do you recall that evidence, Doctor?

A. Yes, I do.

Q. Now I understood the "No, yes." answer at the end to mean that yes, you could not exclude the cause of death, although there was no evidence of it, you could not exclude the cause of death?



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A. That is right.

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Q. Doctor, if a child was known

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to have congestive heart failure during life; if

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the clinicians had observed factors during life

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indicative of that condition, I take it that you

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would see signs or indicators at autopsy of that

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condition?

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A. That is correct, yes.

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Q. And you would also expect

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the pathologist performing the autopsy to see some

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indication of that condition reflected in the

12

clinical history of the child that is provided to

13

you at the time that you undertake the autopsy?

14

A. That is correct, yes.

15

Q. Doctor, is it not also

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possible that heart failure, what Mr. Scott

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described as pump failure, could be caused by

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something other than the anatomical defect which he

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suggested to you yesterday? What I mean by that

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is that the pumping action of the heart can simply

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stop if an administration of a massive dose of

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a poison such as digoxin was administered, that too

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would cause the heart simply to stop; would you

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agree with that?

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A. No, it is not that simple.

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As far as what the pathologist sees at autopsy is an indication of what would be called a chronic heart failure. In other words, you have to have some, to allow some time for these changes to develop. Here we are talking about chronic heart failure of days, weeks, months.

Q. Yes.

A. And this would not be an uncommon finding in cases with congenital heart disease.

Q. Yes, I understand.

A. Where there is sort of a gradual pump failure.

Q. I understand that there is a distinction, Doctor.

A. Yes.

Q. I understand there is a distinction in a situation where a patient has had chronic heart failure or what I chose to call congestive heart failure.

A. That's right.

Q. And in that situation you have told me that if an autopsy was performed you would expect to see signs of that?

A. Yes, you would see signs of



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that, yes.

Q. Then the other situation, the distinction I understood to be drawn yesterday was the situation where there is instantaneous death and pump failure. I understood you to say in that situation you would not expect and normally would not see pathological findings suggestive of pump failure, that is the other situation; is that correct?

A. Yes, this would refer to say a normal person with sudden pump failure.

Q. Yes.

A. Then you wouldn't see these changes in the organs. But if you are talking about a patient with chronic congestive heart failure who died suddenly for other reasons than his heart disease, then you would still see the changes of heart failure.

Q. All right. That is my point, Doctor.

A. Yes.

Q. If there are two distinct situations.

A. Yes.

Q. And the first is one where the patient has been recognized during life to suffer



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from heart failure, or congestive heart failure.

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A. Yes.

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Q. Then you will see signs of

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that at autopsy?

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A. That is correct, yes.

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Q. That is situation number one,

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right.

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A. Yes.

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Q. Situation number two is where

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the patient dies instantaneously, and in that

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situation you have told us you might not see

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pathological findings indicating pump failure at

autopsy, is that correct?

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A. Well, this would refer to a

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patient who has a condition not predisposing to

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heart failure and/or healthy individual.

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Q. My only suggestion to you,

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Doctor, was if at autopsy you were confronted with

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that situation, a patient that was not known to have

an anatomical defect in the heart.

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A. Yes.

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Q. You would, in that situation,

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if the patient had died instantaneously not expect

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to see any pathological indications of pump failure.

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A. That is correct.

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Q. My suggestion to you is that in that situation it is also possible that the heart pumping activity could be caused to stop, thus causing the death of the patient?

A. Yes.

Q. If a lethal dose of a poison was administered, that too would have the result of causing the pump to stop.

A. Yes, I believe so.

Q. And that could be the case with digoxin?

A. Yes, I believe so, yes.

Q. Thank you, Doctor. The second potential cause of death to which your attention was drawn by Mr. Scott yesterday was instability of temperature; do you recall that?

A. Yes.

Q. You told Mr. Scott, as I understood your evidence, that there would no pathological indicators of that kind of a cause of death?

A. Yes.

Q. Doctor, I would take it that we can agree that if the instability of temperature in any particular patient is of and in itself



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triggered by an underlying condition, then you may very well see pathological findings which are suggestive of that condition. For example, if the patient has an overwhelming infection, that might result in instable temperature readings, correct?

A. Well during infection you would tend to have high temperature, but that would not be interpreted as unstable temperature.

Q. Are there not conditions during life, Doctor, caused by disease, or a condition that could be suffered by the patient, which could result in instable temperatures, or do you know?

A. This would be common in premature small birth weight infants. Due to the small body weight, low reserve and immaturity of the central nervous system that you get this instability, and they tend to get hypothermic, that is they have lower temperatures than what you normally would have.

Q. Are there signs of hypothermia at autopsy?

A. No, you cannot detect it, this is something you observe during life.

Q. Now if we make the assumption



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that the patient involved is not a premature baby.

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A. Yes.

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A. It would be uncommon in older or full term infants or adults, it would be fairly uncommon.

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Q. And if happened, Doctor, and if it was caused by an infection, or a disease of some kind, I take it it is possible that you would see evidence of that infection or that disease at autopsy?

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A. Yes, it would be a secondary type of phenomena, yes.

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Q. Thank you, Doctor. Then thirdly, your attention was drawn by Mr. Scott to four kinds of conduction failures that had been described by Dr. Rowe. Do you recall that?

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A. Yes, I do.

Q. And you told Mr. Scott, as I



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understood it, that at autopsy in your view there would no pathological indicators of those kinds of conduction failures unless a conduction study had been undertaken; do I have that correctly?

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A. That is correct.

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Q. Are you saying, Doctor, in that regard, that in every case, in order to rule out a malfunction or a defect in the conduction system of the patient at autopsy, a conduction system study must be undertaken?

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A. Well, I think it depends on the facilities at the time and money available to do such a study. As was mentioned before it requires a considerable ---

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Q. Time, expenditure and financial concern as well?

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A. That is right.

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Q. Leaving aside, Doctor, the difficulties in undertaking this study.

A. Yes.

Q. My question to you was, was the import of your answer yesterday intended to mean or to convey that at autopsy as a pathologist, you would be unable in any case to rule out a conduction system defect, or a conduction system abnormality



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without a conduction system study being undertaken?

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A. That is correct.

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Q. Does that mean, Doctor, that

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at every autopsy that you performed, you cannot

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with certainty say that the cause of death might

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not have been a conduction disturbance, because we

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know that those conduction studies have not been

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done in the Hospital?

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A. Well, there has to be some

degree of suspicion that this actually happens.

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There would be clinical and electrophysiological

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indicators which would tell you this patient had

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this disturbance.

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Q. Is it not possible, Doctor,

as well, that at autopsy as part of the pathological

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findings you might see evidence of an electrolyte

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imbalance, or a conduction disturbance, that that

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is something you might see as part of the test,

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the detailed test that are conducted in a normal

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autopsy?

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A. No, you would not see that.

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Q. You would not see that?

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A. No.

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Q. No electrolyte tests are

done as part of the normal autopsy procedures?

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A. Well, it's being done on a selective basis.

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Q. And if they were done, Doctor, and if irregularities were shown as a result of those tests, would that not suggest to you as a pathologist that there might be some conduction disturbance?

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A. I don't see the connection between the electrolytes and the conduction, I don't think there is any connection.

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Q. Doctor, then if the electrolyte readings will not provide you with that kind of a basis, is there any other way at autopsy in which you as a pathologist could determine whether or not a conduction disturbance had been sustained by the patient involved without relying purely on what had been observed during life?

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A. I think the purpose of the pathology examination would be to correlate the observation in life which would be the electrophysiological abnormalities with actual anatomic findings, structural findings in the conduction system.

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Q. Then I take it, Doctor, that you can rule out a conduction failure, or a conduction



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disturbance as a possible cause of death without doing a conduction system study, if there has never been any suggestion or any suspicion in the clinical history of the patient of a difficulty of that kind. Is that something you would be prepared to rule out?

A. Well, I think you would not consider it unless there is good clinical evidence.

Q. Thank you, Doctor. And you wouldn't need a conduction system study to tell you that?

A. That is right.

Q. All you would have to do is look at the child?

A. That is right.

Q. Doctor, finally, the fourth cause of death that I will simply draw to your attention that was discussed yesterday between Mr. Scott and yourself as you may recall was apnea.

A. Yes.

Q. Do you remember that?

A. Yes.

Q. As I understood your evidence with Mr. Scott yesterday, you told him that you wouldn't normally expect to see anything at autopsy suggestive of apnea unless a detailed examination of the brain



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had shown changes in the brain; do I have that
correctly?

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A. That's correct.

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Q. Doctor, am I correct that a
microscopic examination of the brain is part of a
normal complete autopsy conducted at the Hospital
for Sick Children?

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A. That is correct, yes.

10

11

Q. So that in the circumstances
of a normal autopsy that detailed microscopic
examination of the brain would be undertaken?

12

A. That is correct.

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Q. And once undertaken, if there
were any symptoms indicative of apnea, as for
example gliosis for scarring of the brain stem, that
would present itself during the course of those
microscopic examinations?

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A. Yes.

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Q. And in that sense, Doctor,
can we agree that by the time you complete a
normal routine autopsy on any patient at the
Hospital, if that patient has suffered apnea during
life you would well expect to see some indication of
that in the brain based on the microscopic examination?

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A. Well, I think it is not as



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simple as it is put. But you know a neuropathologist
and a pathologist trying to make an association, and
apnea means stoppage of breathing, this is something
you observe.

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Q. Yes.

7

A. And in doing autopsies on
patients who died, you know, with these kinds of
symptoms, usually you see repeated apneas, and this
happens again with premature babies who tend to
suffer from this, low birth weight babies. Then you
try to correlate, you know, you know these were the
symptoms and the pathological examination you look
at the changes which might explain these clinical
symptoms of apnea, and the association which has
been made is that the changes in the brain stem
which we know are the centres of respiration, but
this is hypothetical.

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You can verify it to an extent in an experimental animal but to be saying that if there is a patient who suffered with apnea and he doesn't have the lesions in that particular area, it doesn't rule it out.

Q. No, I accept that, Doctor, perhaps I put the question badly. Can we agree, can we go this far together, that apneic spells are commonly associated with hypoxia. Would you agree with that?

A. Well, that would be part of the whole syndrome.

Q. All right. And would you agree with me that at autopsy if a patient had, if the cause of death was apnea, if an apneic spell had been suffered and the patient was suffering from hypoxia there are indicators which would be evident at autopsy of a hypoxic condition?

A. Yes, if it is chronic enough, if there is a long enough duration then you might see it, yes.

Q. All right. And similarly, and perhaps the fairest way to suggest this to you, Doctor, is that Dr. Becker has testified extensively with respect to what he regards as being the pathological



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1
2 indicators of Sudden Infant Death Syndrome and missed-
3 SIDS and he has indicated in that regard that one of
4 the factors which indicates apnea and hypoxia is
5 gliosis or scarring of the brain and that he would
6 expect in that circumstance to see that at autopsy.
7 My suggestion to you only is that if apnea has been
8 suffered you might very well see as a result of the
9 detailed examination of the brain evidence of gliosis
10 or scarring of the brain and as well evidence of
hypoxia?

11 A. Yes, that would be in a typical
12 case, and this again is not a thing you will find in
13 a hundred per cent. I think it probably came out thus
14 far that the medical knowledge is not ---

15 Q. I understand your evidence,
16 Doctor.

17 A. --- complete and we are really
18 dealing with hypothesis.

19 THE COMMISSIONER: Just a moment.

20 MS. CRONK: Perhaps to anticipate ---

21 MR. ROLAND: Yes. I am sure my friend
22 didn't leave this out of her interpretation of
23 Dr. Becker's evidence on purpose but as I recall
24 Dr. Becker he also said that the spells had to occur
25 at least two weeks before the death or the autopsy to



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show up even as indicators where, as my friends have indicated, as an indicator, that is, if the apneic spell occurred within two weeks of the autopsy there likely would be no indicators.

MS. CRONK: That's fairly put, thank you, Mr. Roland.

Q Doctor, the only point and then I will leave this issue is, in your opinion and your evidence has been that if periods of apnea are experienced during life and the time interval is sufficient between the time that the apneic period is suffered by the patient and the time of death, in those circumstances you would expect to see evidence of that at autopsy?

A. Yes, you would.

Q All right. And in that sense you would agree with Dr. Becker?

A. Yes, I would.

Q All right. And similarly to be fair, as Mr. Roland points out with respect to evidence of hypoxia, if the patient had suffered hypoxia and given a sufficient time interval you would expect to see evidence of that at pathology?

A. Yes.

Q At autopsy, I'm sorry.



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A. Yes, you would.

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Q. All right. Doctor, I would ask you to make the assumption that at autopsy you find evidence of both those factors of apnea or apneic spells during life and as well evidence of hypoxia. Do you understand the assumption?

7

A. Yes.

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Q. I am asking you to assume that you find that evidence at autopsy?

10

A. Yes.

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Q. All right.

12

THE COMMISSIONER: I am sorry, could I just interrupt for a moment?

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MS. CRONK: I'm sorry.

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THE COMMISSIONER: What would the nature of the finding of hypoxia in life, where would you find it, what would be demonstrated?

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MR. TOBIAS: Excuse me, Mr. Commissioner, I didn't hear your question to the witness.

18

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THE COMMISSIONER: No. Well, it was - you can perhaps incorporate the question in the answer do you think. Where would you find evidence of, how would you find or how would the existence of hypoxia be demonstrated on an autopsy?

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THE WITNESS: Well, actually these

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findings are based on a rather large study from the
United States by Dr. Naeye, who examined several
hundred ---

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THE COMMISSIONER: I don't want you to
go into a great deal of detail. I want you to say
whereabouts in the body.

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THE WITNESS: Yes.

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THE COMMISSIONER: How do you find - when
a child lacks oxygen how do you find ---

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THE WITNESS: Yes, but what I would
like to explain is that this study is based on a large
number of patients dying of crib death and by doing
detailed morphometric measurement studies in these
cases, this study came to the conclusion that these
babies have increased fat, they have thickened pulmonary
arteries.

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THE COMMISSIONER: Those are all the
same symptoms that Dr. Becker said?

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THE WITNESS: That's correct, yes. This
is assumed to be on the basis of, or the hypothesis
proposed was that these changes are due to chronic
hypoxia, alveolar or pulmonary hyperventilation in
these patients. So, this is a finding which is based
on a study and which is not a hundred per cent accepted
by everybody in the field.

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THE COMMISSIONER: No, but hypoxia is lack of oxygen and apnea is lack of breath. Are they the same things?

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THE WITNESS: Well, apnea would lead to lack of oxygen.

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THE COMMISSIONER: You can't I take it have a lack of oxygen. As long as you have breath there is lots of oxygen in the air, is that the thought?

8

9

THE WITNESS: Well, you can have hypoxia if you go to a high altitude then the oxygen is ---

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11

THE COMMISSIONER: And you lack the oxygen that comes in the air?

12

13

THE WITNESS: That's right.

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THE COMMISSIONER: But that is not in The Hospital for Sick Children?

15

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THE WITNESS: No.

17

THE COMMISSIONER: They keep an adequate supply of air there?

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THE WITNESS: That's right.

19

THE COMMISSIONER: Well, when a doctor refers to hypoxia and refers to spells of apnea. Is he talking about the same thing?

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THE WITNESS: No, spells of apnea would be the ones which lead to hypoxia. Like, if these spells are of a long duration --

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THE COMMISSIONER: Yes.

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THE WITNESS: -- then that would lead

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to chronic ---

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THE COMMISSIONER: Apnea is the disease
and hypoxia is the result of the disease?

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THE WITNESS: Is the consequence of it,

7

yes.

8

THE COMMISSIONER: All right.

9

MS. CRONK: Doctor, just to explore

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that briefly so I understand further.

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THE COMMISSIONER: I interrupted your

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question but I would think the answer then becomes
fairly obvious.

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MS. CRONK: That's fine. One more

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question on that if I may, Mr. Commissioner.

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THE COMMISSIONER: All right.

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MS. CRONK: Q. Doctor, just for purposes

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of illustration.

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A. Yes.

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Q. In the Kevin Pacsai preliminary

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autopsy report, for example.

21

A. Yes.

22

Q. You include reference to this

23

finding: hemorrhages on the thymus and recent

24

hemorrhage of, and I may be mispronouncing it, falx

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E.8

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cerebri are most likely related to hypoxia. Do you recall that finding?

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A. Yes.

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Q. Were those findings not in fact indicators at autopsy of hypoxia in that child?

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A. Well, this again is in the context of trying to explain those findings and, as I understood the infant Pacsai, when he was admitted to the Sick Children's Hospital he had suffered a cardiac arrest and was resuscitated. So that he had a period of hypoxia and I was tying these two things ...

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Q. Together.

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A. Together, yes.

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Q. When you observed those hemorrhages in those locations at autopsy, Doctor --

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A. Yes.

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Q. -- did that not suggest to you, was that not regarded by you as being evidence of the hypoxia that you knew had been experienced during life?

18

19

A. Well, these would be signs like hemorrhages, these would be signs of acute hypoxia.

20

Q. Thank you, all right.

21

A. As opposed to chronic.

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23

Q. That is one kind of pathological indicator in this case of acute hypoxia?

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A. That's right, yes.

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Q. All right. And similarly, Doctor, can we agree that gliosis or scarring of the brain stem is a factor that would be commonly regarded by pathologists as being an indicator of apnea?

8

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A. Well, it is thought to be the basis of apnea.

10

11

Q. All right. And if you find that you think apnea?

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A. Well, you would think that, you know, this patient should have had apneas.

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Q. Thank you.

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A. Now, you have a case where you find these lesions and yet there is no clinical evidence that he suffered from apnea?

Q. And that I take it doesn't mean that the patient didn't?

A. That's right.

Q. I guess it could be acute apnea?

A. It was not observed.

Q. It could be acute apnea?

A. No, these lesions you only get after chronic apnea of several weeks' duration.

Q. So, it may have happened and simply not been detected?

A. That's right.



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Q All right. But when you see that finding that's what you think of?

A That's right, yes.

Q All right. Doctor, one final area, and this relates to, again, the postmortem sample that was taken for digoxin assay in respect of Kevin Pacsai.

A Yes.

Q You will recall during the course of your cross-examination by Ms. Forster yesterday, as I understood the exchange, you suggested that bacterial contamination of that sample might be possible from the surrounding air. Do you recall that?

A Yes.

Q And it is because of that possibility, as I understand it, Doctor, the possibility that bacteria in the air can contaminate a sample that's been taken that pathologists when they take samples for cultures sterilize this site by using a heated instrument, that is exactly why they do it, is that right?

A Well, no, the sterilization is for the purposes of sterilizing the area where you puncture, where you make the puncture and enter the vessel and there may be contamination from postmortem



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bacteria overgrows, or, you know, you contaminate it when you cut into it, into that area. So, it would be analogous to when blood was drawn from an arm, you know, you sterilize it before you draw the blood.

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Q. All right.

7

A. It's the same sort of thing.

8

Q. I'm sorry?

9

A. You know, it is the same kind of reason.

10

11

12

Q. All right. And that is done, as I understood your evidence, Doctor, for the purposes, or at least when a sample is being taken for culture?

13

A. Yes.

14

15

Q. All right. And is it felt that that sterilization process reduces the risk of bacterial contamination of the sample?

16

A. Yes, I would think so.

17

18

19

Q. All right. And was that form of sterilization in fact undertaken with respect to Kevin Pacsai before that sample was taken?

20

A. Yes.

21

22

Q. All right. And you told Ms. Forster as well that when the cultures that were sent on Kevin Pacsai came back they were in fact negative?

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A. That is correct, yes.

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Q. All right. Would you agree with me, Doctor, that based on those two factors, first, that that sterilization technique was used with respect to that sample for the purposes as you have outlined and, secondly, that the cultures when actually tested were negative, but those two factors in combination make it improbable that that sample on Kevin Pacsai was contaminated by any bacteria in the air?

A. Yes.

Q. Thank you, Doctor. Thank you for your patience, Doctor.

Oh, there is one final matter, Mr. Commissioner, and I hope it is something to which my friends have no objection. During the course of my discussions with Dr. Cutz he informed me with respect to the case of Allana Miller that the neuropathological tests that had been done as part of the autopsy on Allana Miller had in fact been in part carried out by Dr. Becker. His evidence before you, sir, was that the results came back essentially negative, that there was nothing significant in that report and he has provided me now with a copy of the report. It is entitled "Neonatal Neuropathology Check List". Unless my friends have any objection I propose to ask



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Dr. Cutz to identify the report and have it marked at
this stage while he is available to identify it for us.

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THE COMMISSIONER: Yes, all right. It
is difficult for them to indicate that without seeing
it first I would think. However --

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6

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MS. CRONK: Is that the report, Doctor,
which you received from Dr. Becker, being the results
of the neuropathological testing on Allana Miller?

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9

THE WITNESS: Yes. This would be
actually a rough sheet.

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11

MS. CRONK: Q All right. And that you
received from Dr. Becker?

12

13

A. Yes.

14

Q All right. Is there a more
formalized report in complete form?

15

16

A. There should be a typed one.

17

18

Q Perhaps through your counsel you
can provide that to us if you have a copy of it but
for the moment, sir, I would ask that this be marked
as it is the only material that has been provided to me.

19

20

THE COMMISSIONER: Yes, all right,
Exhibit 208.

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--- EXHIBIT NO. 208: Document entitled: Neonatal
Neuropathology Check List".

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THE COMMISSIONER: All right.

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MS. CRONK: Doctor, thank you very much
for your patience.

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THE COMMISSIONER: Yes.

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MR. TOBIAS: Mr. Commissioner, I am
sorry to make this request but I have some short
questions, I would be less than five minutes, arising
directly out of the territory covered by Miss Cronk
in her re-examination.

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11

THE COMMISSIONER: Yes, all right. I
don't want to make a habit of this, Mr. Tobias, you
know what the rules are.

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MR. TOBIAS: Yes, I am aware of the
rules, Mr. Commissioner, and I have no intention of
making a habit out of it. You will note that this is
the first time I have made such a request.

15

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THE COMMISSIONER: All right. All right,
yes, okay, carry on, Mr. Tobias.

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MR. TOBIAS: All right, thank you, sir.

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THE COMMISSIONER: I don't want you to,
just because we are a half an hour to the regular
break, I don't want you necessarily to drag yourself
out to that point.

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MR. TOBIAS: No, I promise you that I
won't, Mr. Commissioner.

23

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THE COMMISSIONER: You realize of course



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that after that I have to nod, I hope just nod, in
the direction of the three counsel.

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MR. TOBIAS: Yes, I realize that. That
is the reason for my tentativeness and my apology
because of that practical problem.

5

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THE COMMISSIONER: I just want to say
that was the reason for my bad temper.

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MR. TOBIAS: That's fine.

10

FURTHER CROSS-EXAMINATION BY MR. TOBIAS:

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Q. Dr. Cutz, I intend to ask just
several short questions dealing primarily with some-
thing that arose on Miss Cronk's questioning about
apnea and arose with respect to the Commissioner's
questioning. You indicated that apnea is really the
cause of why you would see evidence on autopsy of
hypoxia. Do I understand that correctly?

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A. That is correct, yes.

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Q. All right. Now, you also
indicated to Miss Cronk that if one found evidence of
hypoxia on autopsy without there being any clinical
evidence whatsoever of apnea, one would have to assume
that there were apneic periods that were unobserved.
Do I understand that as well?

A. Yes.

Q. Now, in a situation where you



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have observed periods of apnea and you find brain stem scarring, is it fair, or would you as a pathologist assume that the brain stem scarring is explained by the apneic periods even if the apneic periods took place within two weeks of death?

7

8

9

A. Yes, I think you could try to tie these two things together, yes. But as I mentioned before you need some minimum time before you start to see these changes.

10

11

12

13

Q. All right. Well, let me go back just for a moment. If you saw signs of hypoxia without any observed periods of apnea during life, what conclusion would you draw?

14

15

THE COMMISSIONER: How do you mean by signs of hypoxia? You mean if you saw this ---

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MR. TOBIAS: On autopsy, at post mortem examination.

18

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THE COMMISSIONER: You saw damage to the brain stem?

20

21

MR. TOBIAS: Well, brain stem scarring and thickening of the pulmonary arterials and persistence of brown fat, those are the particular markers.

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Q. If you saw all of those on autopsy but they were absolutely - there was nothing in the medical record to indicate that there had been



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an observed period of apnea, what conclusion would
you draw?

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A.

Well, I think what you are

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referring to would be a case which a pathologist would

6

classify as Sudden Infant Death Syndrome or crib

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death.

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Q. Yes.

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A. This is not uncommon that

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these things are not observed. The babies appear

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perfectly normal. These abnormalities usually occur

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during sleep or that is what the hypothesis is.

7

Q. All right. Are you indicating

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therefore that you could draw a conclusion of crib

9

death without making an assumption that there had

10

been unobserved periods of apnea, or would that be

11

implicit in your diagnosis?

12

A. Well, if the baby and all

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the remainder of the history and the findings would

14

point to the diagnosis of crib death, and you would

15

find evidence of hypoxia on these various organs

16

that would strengthen your diagnosis as being crib

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death.

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Q. All right. What I am

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specifically asking you, though, is this: in coming

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to that diagnosis of crib death would you be

21

implying in your own mind that there had been some

22

periods of apnea that were simply not observed?

23

A. That is correct.

24

Q. All right. Now you also

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indicated I believe in answering Miss Cronk's question

that the various indicia of hypoxia which



1
2 are commonly seen in crib death and which Dr. Naeye
3 identified is not something that is universally
4 accepted.

5 Do you agree with that?

6 A. Yes.

7 Q. All right. If you saw evidence
8 of hypoxia in a child and there had been periods of
9 apnea during life, would that in your opinion be
10 sufficient to support the pathological diagnosis of
11 crib death? In the absence of any other pathological
12 explanation for death I should say?

13 A. Yes. I think that would be
14 a primary diagnosis.

15 Q. That would be your primary
16 diagnosis? Now is that not because crib death is
17 a diagnosis of exclusion?

18 A. That is correct.

19 Q. And I have given you in my
20 question, I have asked you to assume that there was
21 no other indication of any other cause of death.
22 Is that correct?

23 A. Yes.

24 Q. So that would be a very large
25 part of the reason for your coming to that diagnosis?

A. Yes, I think it kind of



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1
2 depends on the extent and detail of the examination
3 and the experience of the person performing it.
4 Q. Well let me ask you this
5 directly: let's take the same identical example,
6 Doctor, where there were observed periods of apnea,
7 and there were the various pathological indicia of
8 crib death.
9 A. Yes.
10 Q. You also saw evidence of
11 chronic heart failure. Would that cause you not to
12 make a diagnosis of Sudden Infant Death Syndrome?
13 A. Well, you would have to
14 explain the reason for chronic heart failure. One
15 possible reason could be chronic, quite profound
16 chronic hypoxia.
17 Q. Did I say - I am sorry,
18 Doctor, I think I have confused the issue by saying
19 chronic heart failure. If you in that example also
20 saw pathological evidence of congestive heart failure,
21 would that cause you to go away from the diagnosis
22 of SIDS because you had found another pathological
23 cause for death?
24 A. Well, I think the classical
25 crib death the patient is just found dead. There
is no medical or other observations.



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Q. Yes, I understand that entirely. I am asking you to make an assumption, and the assumption is that you have the hypoxia ---

A. Yes.

Q. - you have got observed periods of apnea and you as well have pathological evidence of congestive heart failure.

Now in that particular example you have the other explanation. You haven't excluded all other explanations. Would that cause you to go away from the diagnosis of Sudden Infant Death Syndrome?

A. Not necessarily because you have cases where it is called an aborted SIDS where the child is resuscitated.

Q. Yes.

A. And then because of the resuscitation and the damage suffered during the sort of period between life and death you develop complications.

Q. Yes.

A. And this is due to the complications and has nothing to do with the crib death.

Q. All right. Are you



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indicating ---

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A. So this would be, you know,
would not be relevant to the basic disease. This
is something related to the treatment received after
resuscitation.

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Q. All right. I want to make
sure, Doctor, that I understand what you are saying.

8

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Again looking at my particular example
you are saying the evidence of congestive heart
failure might be explained by a previous episode of
heart failure and resuscitation efforts?

12

A. That is correct.

13

14

Q. So you could explain it
away?

15

A. Yes.

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Q. My question specifically is
this, Doctor, and again I realize it is difficult
because I am asking you to make certain assumptions
that you might not see in a pathological setting.
But just for the sake of argument, please, assume
that you could not explain away the congestive
heart failure by evidence of previous heart failure
and resuscitation. Let us assume that it wasn't
there and that there was no other way to explain
away why the chronic failure was there or the



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congestive heart failure was there, would you then agree with me that it would be much more difficult to come to a diagnosis of Sudden Infant Death Syndrome because there was another pathological anatomical cause of death present?

A. Well, as I say, you know, it depends on the criteria one uses to make Sudden Infant Death Syndrome.

Q. That is precisely what I am asking you.

A. Yes.

Q. Is one of the criteria absence of any other cause of death?

A. Well, but it is also the way the child or the infant presents.

Q. I understand that.

A. And once there is some kind of a medical intervention or something then it doesn't rule out that the child suffered from Sudden Infant Death Syndrome.

Q. Yes, Doctor, and assuming there was no medical intervention.

A. Yes. Then you wouldn't have any records of this as to what happened, and if you find evidence of heart failure then you wouldn't call



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it crib death. You would have to explain it some
other way.

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Q. All right. Fine.

5

Now if you had a situation, Doctor,
where you had the episodes of apnea observed during
life ---

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7

A. Yes.

8

9

Q. - it would be fair to assume
from that that there may have been episodes of apnea
during life that were not observed?

10

11

A. Yes.

12

13

Q. Okay. If you have observed
periods of apnea, a history of difficulty in
breathing ---

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A. Yes.

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Q. - and evidence of chronic
hypoxia, do you agree with me that not every
pathologist would accept that as conclusive evidence
of Sudden Infant Death Syndrome?

18

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A. Well, we would - we at Sick
Kids certainly accept that.

20

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Q. That is fine.

22

A. Yes.

23

Q. But I am going back to your
statement before.

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A. Yes.

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Q. That it is not universally

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accepted by pathologists everywhere. That was your
evidence, was it not?

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A. Well, this is a scientific
debate discussing the results obtained.

7

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Q. Exactly. And not everyone
agrees with the conclusions that you draw from that
debate?

9

10

A. That is right.

11

Q. Is that correct?

12

A. Yes, so there are certain
people who draw conclusions based on their own
experience.

13

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Q. All right. Fine.

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16

A. And who may or may not agree
with the study.

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MR. TOBIAS: Thank you very much,

18

Doctor.

19

THE COMMISSIONER: Mr. Roland?

20

MR. ROLAND: I haven't heard anything
that I didn't already know from Dr. Becker so I have
no questions.

21

22

MR. ORTVED: I have no questions.

23

THE COMMISSIONER: Miss Cronk?

24

25



9 1 MS. CRONK: No, sir.

2 THE COMMISSIONER: All right. Thank

3 you, Doctor. Thank you very much, for the second or

4 third time.

5 Do you want to take a break now?

6 MS. CRONK: That is fine.

7 THE COMMISSIONER: Well, it is to suit

8 you.

9 MS. CRONK: If we can take it now

10 we can proceed right through to one o'clock, and I

11 am content that we do that.

12 THE COMMISSIONER: Yes. Well, I think

13 it might be wise if we take 20 minutes now.

14 ---Short recess.

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--- on resuming.

THE COMMISSIONER: Yes, Miss Cronk.

MS. CRONK: Mr. Commissioner, our next witness is Dr. Graham Ellis, who, as you recall, previously testified before you.

Dr. Ellis.

GRAHAM ELLIS, Recalled

DIRECT EXAMINATION BY MS. CRONK:

Q. Dr. Ellis, you were previously sworn in this proceeding and you are still under oath today, sir.

A. Yes.

Q. Dr. Ellis, there are three areas that I would like to discuss with you today.

The first is the general contents of the digoxin books which, we understand, were maintained in the Biochemistry Laboratory at the Hospital under your supervision during the period of time when you were responsible for the digoxin assays that were being conducted and, as well, the contents of the various clinical chemistry computer printout forms that we have been reviewing since you last testified.

The second area is your involvement by way of supervision of various digoxin assays



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that were conducted on specific children in the
timeframe with which we are concerned; July of 1980
to March 1981, in respect of blood serum samples
that were tested for digoxin.

Then, the final area is, again
your involvement by way of supervision or otherwise
on digoxin assays that were conducted on either
tissue samples or body fluid samples from those
various children, again during the same time period.

Dealing first, doctor, with the
issue of the contents of the digoxin books maintained
in your laboratory, as I understand it and to
refresh perhaps everyone's recollection, you pre-
viously testified that during the period 1980 to
the end of March 1981, you were responsible for the
radioimmunoassay for digoxin at The Hospital for
Sick Children. Do I have that correct?

A. That is correct, yes.

Q. And the technique you
previously told us was used during that period to
conduct any and all digoxin assays that were per-
formed at the Hospital.

A. Yes.

Q. Do I have that correctly?

A. Yes.



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Q. Doctor, I would ask you to
turn to Exhibit 32B.

And, perhaps, Mr. Registrar,
you could provide a copy to Dr. Ellis.

Doctor, this volume is a complia-
tion of a number of exhibits that were introduced
in evidence at the preliminary hearing in The Queen
vs. Nelles, and I would ask you first to turn to
Tab 45 of that book, which, as I understand it, is
one of the digoxin books maintained in your laboratory
which was marked as Exhibit 45 at the preliminary
hearing. This particular book is expressly to cover
the time period from January 13, 1981 through to
March 25, 1981.

Can you identify this as one of
the digoxin books maintained in that time period in
the laboratory, doctor?

A. Yes. This is a copy of
that book.

MR. TOBIAS: Pardon me, Miss
Cronk. Was that Exhibit 47 at the preliminary hearing?

MS. CRONK: Exhibit 45, I believe.

MR. TOBIAS: If it is the same as
what you have handed out this morning, it is 47.

MS. CRONK: It is not, Mr. Tobias.



Ellis
dr.ex. (Cronk)

G4

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You have the wrong document in your hand. Exhibit 32B, Tab 45, which was also Exhibit 45 at the preliminary hearing.

THE COMMISSIONER: Has everyone not got a copy of that exhibit?

MS. CRONK: Everyone has a copy.

THE COMMISSIONER: Everyone had except me, until today, and now I have it.

MS. CRONK: The greatest oversight of all, sir.

MR. ORTVED: I wonder, did you have to pay as much for it as I did? I got a bill with mine!

MS. CRONK: Q. Doctor, I would ask you, first, after you finish sympathizing with Mr. Ortved, to turn to the cover page of Tab 45.

A. Yes.

Q. We see there, first of all, the numbers "393" encircled.

Could you explain what those numbers refer to?

A. I believe this was the code number for the entry of digoxin in the computer.

Q. At the Hospital?

A. At The Hospital for Sick



G5

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Children.

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Q. Can you help me, doctor.

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Whose responsibility would it be to record in this

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digoxin book, or any others like it which we will

6

see in a few moments, the results of any digoxin

7

assay that had been conducted in the Hospital?

8

A. It would be the technolo-

9

gists in my section.

10

Q. And would you, as part of

11

your responsibilities in overseeing the technologists,

12

have occasion on a daily basis to review the assay

13

results that had been entered in the digoxin book?

14

A. I would have occasion --

15

I would have opportunity to read these on a daily

16

basis. It would frequently be my practice, but I

17

cannot say that every day, vigorously, I read these.

18

Q. I take it, though, very

19

often you did?

20

A. Yes.

21

Q. And in respect of the

22

exact contents of these books, do I take it, because

23

of the code numbers which appear on the book, the

24

393 for digoxin which you have told us is the computer

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number for digoxin assay, that only assays performed

in respect of the drug digoxin would be entered in



G6

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these books?

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A. Yes. I believe that to be
the case.

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Q. Would you turn to the
very first page, then, doctor, if you would - it is
unnumbered. It is the first page behind the cover
page.

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This, doctor, is a photocopy of
the inside cover of the actual digoxin book for this
time period. Once again, we see the code number
for digoxin, "393", and we then see the first entry
at the top of the page, an entry which I take to
read "Specimen should be drawn 0800 hours, pre-
ferably never before 0600 hours".

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Have I read that correctly?

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A. You have read this
correctly, yes.

17

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Q. Can you help me, doctor,
as to what that refers to?

19

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A. This refers to the
desirability of obtaining digoxin samples eight
hours after the dose of digoxin has been given
and, preferably, not before six hours.

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Q. So, we should probably
then, doctor, as you understand it, be interpreting



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that entry to mean, not that the sample should be drawn at 8:00 a.m., 0800 hours --

A. Yes.

Q. -- but, rather, that it should be drawn eight hours after the last dose has been administered; is that correct?

A. That is correct.

Q. And similarly, we should probably be reading the end of that entry as meaning, not that the sample should never be drawn at 6:00 a.m., but, rather, it should never be drawn before six hours after the last dose of digoxin has been administered?

A. Yes.

Q. Doctor, do those two indications accord with your understanding as it then was during this timeframe, July of 1980 to March of 1981, as to what the optimum conditions were for the drawing of the sample for purposes of a digoxin assay?

A. Yes, they would. On very rare occasions, we may go to five hours, but we try to avoid that, if at all possible. Six to eight is regarded as the best time.

Q. Thank you.



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Doctor, do you know who made the entries, these particular entries, in the digoxin book?

A. I don't know, but the writing is -- I think it looks like one of my technologists'; Mrs. McKellar, possibly.

Q. Doctor, the next entry on the page reads, "1.0 to 1.8 maintenance level greater than 2.5 - a toxic level", and on the top left-hand side of the page, we see the short form for nanograms per millilitre. We have heard, in prior evidence - and simply to repeat it now - I take it that all results recorded in this book were measured in nanograms per millilitre and recorded on the basis of that unit of measurement?

A. Yes.

Q. Can you help me, doctor, in terms of your understanding, because you recall that you have given previous evidence in respect of the therapeutic levels of digoxin as you understood them during this time period and also as to the toxic levels, was it your understanding during this period - that is, this book covers January 13, 1981 through to March 25, 1981, was it then your understanding that a maintenance or therapeutic level of



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digoxin would be 1.0 to 1.8 nanograms per millilitre?

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A. I think I gave evidence on this before. My own interpretation would be, as indicated in the Resident's Handbook, with the various ranges that are indicated there.

I am trying to remember how this might have got -- I am trying to speculate as to how this might have got into this book. I believe it was transferred from a previous book which was older than this one, but I think you indicated to me that it wasn't in the immediate predecessor of this book.

Q. Now, doctor, before that gets terribly complicated and to be fair to you, the evidence -- your previous evidence, as I understood it, when you testified originally in these proceedings was that you considered the applicable ranges to be 0.5 to 2.5 nanograms per millilitre as optimal therapeutic range.

Do you recall that?

A. Yes.

Q. And that you considered 2.5 nanograms per millilitre to 3.0 as being an area of overlap?

A. Correct.

Q. And that you considered



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anything greater than 3 as being overdigitalized or toxic, although, even at 2.5 nanograms, you would be a little bit concerned.

Do I have your evidence correctly?

A. Yes. That is a summary.

MS. CRONK: That, Mr. Commissioner, appears at Volume 6, page 907, of Dr. Ellis' evidence.

Q. I take it then, doctor, that whoever made these entries and for whatever reason, the maintenance levels described there are not the ones which, in your view, were being treated as the appropriate therapeutic ranges in your laboratory during this time period?

A. Yes, that is correct.

Q. Similarly, with respect to the toxic level of greater than 2.5, with regard to your previous evidence, I take it you would have no difficulty in agreeing again that anything over 2.5 would cause you some concern?

A. Anything over 2.5, yes.

Q. Although it might not necessarily be a toxic level in any particular case?

A. Yes.

Q. Thank you, doctor.



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Finally, doctor, we see the entry, "Low result report under 0.2".

Could you again explain for us briefly what that means?

A. This just explains that, when this note was written, it was the policy of the Department not to report results if the calculated result was under 0.2. In other words, if the result came to 0.1 or 0.05, the result of 0.2 would have been produced.

Q. And to put that into context, doctor, as I recall your previous evidence, you testified, again during the time period that we are concerned with, that the minimum detection level used at that time in your laboratory for digoxin assay on the radioimmunoassay method was set at 0.2?

A. I recall going into great detail as to how difficult it was to set a detection limit. For the convenience of reporting, that figure of under 0.2 was used in my laboratory at this time.

Q. That was, then, the minimum detection level?

A. No. I am saying this was the level that was used, the lowest level that was



G12

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reported.

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Q. Thank you, doctor.

4

Anything over that, I take it, would be reported at the actual number that had come out as a result of the assay that you conducted?

5

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A. That is correct.

7

8

Q. Doctor, could you turn then to page 2, which is the immediate next page, at Tab 45.

9

10

Do you have that?

11

A. Yes.

12

Can I also point out that, in addition to this information that was contained within the digoxin book, a photocopy of the Resident's Handbook with all the ranges contained therein was available to my staff for access and for any telephone enquiries immediately after the production had gone to that book.

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Q. So, I take it that if there was any confusion in their minds as to which ranges applied, they could first have recourse to this book, the digoxin book itself?

19

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A. For the actual results.

22

23

Q. For the results but, also, for the indication of what the levels were?

24

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A. No.

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Q. I'm sorry?

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A. They would have -- the

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indication of what the levels were would be con-

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tained in the photocopy of the Resident's Handbook,
Biochemistry Section, that was available to them

7

after the Biochemistry Handbook was printed.

8

Q. And they could, as well,

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in addition to having recourse to the Handbook itself,

10

of course, discuss the matter with you if there was

11

any confusion in their minds?

12

A. Yes, that is correct.

13

Q. Doctor, then, on page 2,

14

if you would, we have, as you will appreciate, during

15

the course of evidence introduced subsequent to your
own, we have had occasion to look at these digoxin

16

books and the various entries contained in them, and

17

I am going to ask you, in certain respects, to

18

confirm our understanding as to how some of these

19

entries should be interpreted.

20

First of all, on page 2, you will

21

see the date of "January 15, 1981". There is no

22

magic in my turning to this particular page, doctor.

23

Would we be correct in interpreting that date as

24

meaning the date upon which the assay itself was

25



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G14 2 conducted?

3 A. Yes.

4 Q. Then, doctor, on the
5 left-hand side of the page, the first column, we
6 see what we have been interpreting to be the names
7 of the various patients upon whom digoxin assays
8 were conducted from various samples.

8 A. Yes.

9 Q. Then, in the second
10 column, doctor --

11 A. Well, in the first
12 column, there is a series of letters.

13 Q. I'm sorry, you are quite
14 right - the second column over.

14 Well, what do the letters refer to?

15 A. The letters refer to the
16 number put on the tubes during the batch.

17 THE COMMISSIONER: I'm sorry?

18 THE WITNESS: The number that
19 was written for that particular batch on the tubes
20 as the assay was processed.

21 MS. CRONK: Q. That was the
22 method of segregating the various tubes?

22 A. Yes.

23 THE COMMISSIONER: They seem to

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be alphabetical, too?

THE WITNESS: Yes.

THE COMMISSIONER: So, I take it
it is the order they come in? Is that the idea?

THE WITNESS: It is the order in
which they are run in the batch.

THE COMMISSIONER: I don't think
I quite understand that. Presumably, one would
come in that would have a vial, or whatever it is
they have the blood in.

THE WITNESS: Yes.

THE COMMISSIONER: It would have
the name of the child.

THE WITNESS: Yes.

THE COMMISSIONER: And you would
give it a letter, would you?

THE WITNESS: No. We would give
it a letter at the time of start of the analysis.

MS. CRONK: Q. Doctor, let me
ask you this: If a number of samples arrived in
the laboratory at the same time, or virtually
simultaneously, how are the entries in respect of
those samples recorded in this book? Are they
recorded in the order in which the assays are
conducted or are they recorded in the order in which



G16

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the samples are received?

3

A. In the order in which

4

the assays were conducted.

5

Q. All right. Thank you,

6

doctor.

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THE COMMISSIONER: The order in

8

which?

9

THE WITNESS: The order in which

10

the assay is conducted.

THE COMMISSIONER: Yes.

11

MS. CRONK: Q. Doctor, then

12

you have indicated, quite properly, that the second
column contains patient names.

13

A. Yes.

14

Q. Then, there seems to be

15

a space beside the patient names and the next

16

immediate column for entry of information and, in

17

some cases, we see some descriptive comment per-

18

taining to the sample that is involved; do we not?

19

A. Yes.

20

Q. And then the next column,

21

doctor, on this particular page, for example, under

Item or Specimen C , we see the word "pathology".

22

A. Yes.

23

Q. "Path", which we take to

24

25



1
G17 2 mean "pathology"?

3 A. Yes.

4 Q. And then, in respect of
5 others, an indication of the number of wards.

6 Can you tell me, doctor, what the
7 information contained in that column was intended to
8 mean?

9 A. This is the source of
10 the request and the destination to which the report
11 should be sent.

12 Q. So I take it then, if the
13 sample was received from Pathology and was to be,
14 the results on that sample were to be reported back
15 to Pathology, that is the entry that would be made
16 in this column?

17 A. Yes.

18 Q. And similarly, if a
19 request came in from the ward, the requesting ward
20 would be identified in this column and that is
21 who, in the first instance, would be the recipient
22 of the results once available?

23 A. That is correct.

24 Q. And then, doctor, the
25 next column we see a short form for various dates.

Can you tell me what the informa-
tion in that column refers to?



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A. This is the date of the specimen.

Q. Is that the date upon which the specimen was actually collected?

A. Yes.

Q. You are referring -- I'm sorry, doctor, just back to the previous column. Can you tell me where that information would come from? Where would that be obtained, the indication from which ward or department in the Hospital had requested the assay?

A. This would be on the sample requisition that accompanied the sample to Biochemistry.

Q. And similarly the date?

A. Yes.

Q. And then, in the next column, doctor, we see various times. What do those times refer to?

A. Those times relate to the time at which the blood was drawn on the date indicated to the left.

Q. That is the time at which the sample was taken?

A. Yes.



G19

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Q. And, once again, where

would you draw that information from?

A. In 99 per cent of cases,

that information would be directly transcribed from
the requisition.

Q. And if the requisition

form, for any reason, was not completely filled out,
or was deficient such that the time of the sample
collection was not indicated, or the date of the
sample collection was not indicated, what, then,
would you do in your laboratory, if anything, to
determine when and at what time the sample had been
obtained?

A. We would probably not do

anything in that, on this particular occasion, you
see, the sample from Pathology, Sample C, there is
nothing in that particular column to indicate the
time at which it was taken.

Q. Yes.

A. And unless the result is

abnormal, there is no real need for us to go and
check it.

Q. And if the result was

abnormal in some respect, would you then make
further enquiry to determine when and at what time



G20

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the sample had been taken?

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A. That could well -- yes.

4

That could well have happened.

5

Q. I take it it is possible

6

but was it the norm? Was that the policy in the laboratory, that those enquiries should be made if a result was irregular or an abnormal result was achieved?

9

A. Yes. I think that would

10

be usual. Yes, pathology specimens are unusual,

11

okay, so I am not saying that would necessarily

12

be the case for pathology samples.

13

Q. Unusual in this particular

14

sense that they were taken at autopsy?

15

A. Yes.

16

Q. So, doctor, then,

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throughout this book, whenever we see a dash in

18

any particular column of information, are we then

19

properly to conclude the information simply wasn't provided to the lab?

20

A. In the majority of cases,

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I would think, yes.

22

Q. Doctor, in the next

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column we see a number of what we have taken to

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be sample numbers. Does that column set out the

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number assigned to particular samples sent for
assay to your lab?

A. Yes. This sample -- this
number was the number on the sample requisition.

Q. Yes.

A. The sample requisition
has attached to it sticky labels with the same
number on them and these sticky labels are usually
attached to the tube of blood taken and, so, there
is a positive identification between the tube of
blood and the sample requisition.

THE COMMISSIONER: Attached by whom?
You, doctor?

THE WITNESS: No, by the wards
that are drawing the blood, or the person who is
drawing the blood.

MS. CRONK: Q. So, those
requisition forms then, I take it, are available
throughout the Hospital to be completed on the
ward or in the various departments if a sample is
going to be taken and sent to the lab for assay?

A. Yes.



H/BB/ak

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Q. All right. So, it is not a situation where the requisition form would be filled out in a normal case in the lab itself, but rather would have been filled out at the time the sample was taken?

A. That's correct, in the normal case, yes.

Q. All right. Then, Doctor, we have seen in a number of cases that the actual numbers assigned to any particular sample are proceeded by a letter, in some cases it is G and in some cases it is H and in some cases it is J and in some cases it is D. Can you tell me, is there any particular purpose in having a different letter precede the sequence of numbers that are assigned to any given sample? Is there any significance to that?

A. There is no major significance. It indicates a different printing run of the whole batch of requisitions.

Q. Thank you, Doctor. And then finally in the last column, the second to last column, again, we see a number of initials and perhaps we can deal first with Sample No. D for a patient known as Amber Moore. We see the letter V,



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what does that refer to?

3

A. This refers to the fact that this was a venous blood sample, as indicated on the sample requisition.

4

5

6

Q. All right. Then I take it the information in this column refers to the type of sample involved?

7

8

A. Yes.

9

10

Q. All right. And with a V it is venous?

11

A. Yes.

12

13

Q. All right. What is the A stand for?

14

A. Arterial.

15

16

Q. All right. And we see on that page as well an O. What does that stand for?

17

18

19

A. O means that either it may not be venous or may not be arterial or the exact type of the sample may not have been indicated to us on the requisition.

20

21

Q. So, I take it then that it could mean either one of two things: either you don't know what type of sample is involved.

22

23

A. Yes.

24

25

Q. All right, or it is something



H3

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other than a blood sample, from a vein or from an
artery.

3

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A. Yes, I think it basically means
there is no specific indication in the appropriate
location as to what that sample is.

5

6

7

Q. And the appropriate location
being a place to indicate that on the requisition.

8

9

A. Being three boxes on the
requisition, yes.

10

11

12

13

Q. All right. Doctor, we have
also seen, although there isn't one as it appears
on this page that I can immediately notice the
letter C in that column. What does that stand for?

14

A. Capillary.

15

Q. All right.

16

THE COMMISSIONER: I'm sorry, C stands
for what?

17

THE WITNESS: Capillary blood sample.

18

THE COMMISSIONER: Capillary.

19

20

21

22

MS. CRONK: Q. And then finally,
Doctor, the next column over the final column in
this particular page we see what appears to be
obvious is the result of the particular assay?

23

A. Yes.

24

Q. All right. And where numbers

25



H4

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appear in that context once again they are always expressed or were during this time period in nanograms per millilitre?

A. That is correct.

Q. All right. Can you tell me, Doctor, what the letters RPT refer to?

A. They indicate that a result had not been produced on that particular sample and it was necessary to repeat that sample.

Q. All right. Does that mean, Doctor, for example, and we will come back with more particularity to the Estrella case, but we see RPT beside Sample C on Janice Estrella, does that mean that that particular sample was beyond the maximum measurement of the assay and required further dilution and further assay to achieve a result?

A. Are you asking if that specific sample or ---

Q. Generally. Generally when the letters RPT are there.

A. Generally that is one explanation. The other explanation would be if - it was our usual practise to analyze in duplicate. If in fact the duplicates agreed badly then it would be necessary to reanalyze that sample again to obtain



H5

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a satisfactory result.

3

Q. All right.

4

A. Under those circumstances we would then still put repeat in that particular box.

5

6

Q. I'm sorry, Doctor, if you say the two duplicates agreed badly, I take it you mean that there was some meaningful discrepancy between the results on each?

7

8

9

A. Yes.

10

11

Q. All right. And in that case you would reassay again in duplicate to see what the result was again the second time?

12

13

A. Correct.

14

15

Q. All right. Doctor, we have sometimes seen as well the letters NSQ in that column. We have been interpreting them to mean not sufficient quantity, is that correct?

16

17

A. That is correct.

18

19

Q. All right. And as well, Doctor, we have sometimes seen before a particular number the symbol for greater than the number that is involved, but we have also seen, as we see on Item H under January 16th the letter X before a number. Do you see where it says X 4.7?

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21

22

23

A. Oh, yes, yes.

24

25



H6

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Q. All right. Can you tell me what the X means?

A. The X means the same, greater than.

Q. All right. Doctor, we have also seen a symbol which, depending on who is trying to interpret it, sometimes looks like a WO.2 and sometimes like a UO.2. There isn't one as it happens on this page but can you tell me first of all which symbol it is and, secondly, what it means?

A. Yes. It really means under, it is U, capital U.

Q. All right.

A. And this is just within the laboratory for convenience. There is always a problem wherever you go in terms of less than and greater than signs. People can never remember, or this has been my experience.

Q. They don't think of them like little arrows?

A. No, they don't.

Q. I see.

A. Or even less than is an L on its side slightly.

Q. Well, just simply by way of



1

2

illustration, Doctor, and we will come back to this.

3

Could you just quickly flip to page 30 of the same

4

digoxin book. Do you have that?

5

A. Oh, yes.

6

Q. Sunday 22nd of March, 1981.

7

A. Yes.

8

Q. Now, we will come back to

some of the --- I'm sorry, sir?

9

THE COMMISSIONER: page 30 you said,

10

of what?

11

MS. CRONK: Page 30 covers the

12

entries for Sunday, March 22, 1981.

13

THE COMMISSIONER: On what?

14

MS. CRONK: Still the same tab, sir.

15

Still Tab 45.

16

THE COMMISSIONER: Oh, I see, I

managed to skip into Tab 46, I'm sorry about that.

17

MS. CRONK: I see.

18

Q. We will come back to these

19

entries later, Doctor, with respect to the particular

20

results and the entries that are recorded, but if

21

we look for example under Item No. 13 through to

22

Item 16 on page 30. Do you see that?

23

A. Yes.

24

Q. All right. We see there the

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H8

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result, and I confess I can't tell whether it is a
W or a U 0.2, but I take it that you are now telling
us that that is a U?

A. Yes.

Q. And it stands for under?

A. Under.

Q. So that if we were to look at
those readings it would be under .2 or under 0.2?

A. Yes.

Q. All right, Doctor.

A. And that would be the entry
put in by our keypunch people into the computer.

Q. A 'U'?

A. A 'U' or an 'X'.

Q. All right.

A. And the computer would then
produce not U or X but less than or greater than,
appropriately.

Q. Thank you, Doctor. Mr. Registrar,
could you show Dr. Ellis if you would Exhibit 106,
which is the medical record for Kevin Pacsai.

Doctor, could you turn please to page
83. Do you have that, Doctor?

A. Yes.

Q. All right. Doctor, this



H9 1
2 document is entitled "A Clinical Chemistry Cumulative
3 Report - The Hospital for Sick Children", and it
4 appears to be, at least has been described to be a
5 computer printout. Can you tell me first who
6 generates these reports?

7 A. These are produced in bio-
8 chemistry by our clerical staff.

9 Q. All right. And when you say
10 they are produced in biochemistry, does that mean
11 that the actual document with all of the information
12 contained in it is physically printed and distributed
from the biochemistry laboratory?

13 A. I think that currently that
14 is the case, yes.

15 Q. All right. Talking in the
16 time period, July, 1980 through March of 1981, was
that the case then?

17 A. These are all produced from
18 a central computer which has various printers on
19 it. I cannot tell you specifically whether at that
20 particular time the computer printout was produced
21 by a computer in the Computing Department or a
22 printer in the Biochemistry Department.

23 Q. All right. Wherever the
24 form itself was produced, Doctor, would I be correct
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H10

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in assuming that the information that is recorded on the document came from the biochemistry lab?

A. That is correct.

Q. All right. And was it part of the responsibilities of the administrative staff in the biochemistry lab to take the results of any particular assay from the digoxin books where they have been recorded and to program them into or to provide them to the computer data base at the Hospital in order that these forms could then be generated?

A. Yes, the clerical staff.

Q. Doctor, I would like you briefly to explain the meaning of a number of the entries on these forms and, again, not with any particular reference to Kevin Pacsai, but at the top right hand side of the page you will see that there is a timing indication and a date. Can you tell me, Doctor, are we correct in interpreting that to mean the time and the date upon which the form itself was produced?

A. Yes.

Q. All right.

A. The piece of paper itself.

Can I just come back to that statement that I made



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in that on occasion technologists themselves go to the computer terminals and put results in but frequently it is the clerical staff who do this.

Q. Those would be technologists from the biochemistry lab though?

A. Yes, that is correct.

Q. All right. Doctor, we see as well across the top of the page a series of categories with particular information set out. It includes the name of a particular patient, what we have been taking to mean the admission number, the history number, an indication of the sex of the child and the birth date of the child and the admission date. Can you tell me first where that information comes from?

A. This information comes from the central computer for which there are terminals in the admission area.

Q. I'm sorry, Doctor, perhaps I put the question badly. I had understood you to say that either the administrative personnel or, as you further explained, the technologists from the biochemistry lab would be responsible for programming the results of any particular assay into the computer data base in order that these forms



1
2 could be generated. Do I have that correctly?

3 A. That is correct.

4 Q. All right. Therefore, would
5 people from the Biochemistry Department as well
6 provide to the computer the information necessary to
7 indicate the admission number for any particular
8 patient, the birth date of any particular patient
9 or the history number for any particular patient,
10 or is that information already stored on the data
base?

11 A. I believe that is already
12 stored on the data base.

13 Q. All right.

14 A. There will be some patients
15 in the Hospital who never go to the Biochemistry
16 Department and yet whose records are being accumulated
17 in the computer and who have received an admission
number and who have this information available.

18 Q. All right. Doctor, the
19 final category of information in that column,
20 reading across the page is an indication of the
21 ward. In this case it happens to be 4B. Can you
22 tell us what significance that entry has?

23 A. Well, this is the ward to
24 which the patient was admitted and provided that the
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patient hasn't moved very recently, that is the ward where the patient is located.

Q. All right. That is not then I take it an indication as to the ward which was intended to receive the document reporting the assay result, but rather it is an indication of the ward to which the patient was last admitted.

A. It is the responsibility of the ward to make sure that the information that we have is updated as quickly as possible afterwards. So, when the child is admitted an addressograph plate, a plastic plate is very often prepared with all this information contained on it from which requisitions, this identification information is transcribed.

Q. All right. My only point was, Doctor, does the information in that column indicate to you and your lab the identify of the ward or the department within the Hospital who is to be informed of the results of the assay?

A. On this particular sheet of paper?

Q. On any printout of this kind, when you look to that column and see an indication of a particular ward, does that mean to you or does



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that identify for you as the biochemist responsible for these assays, the ward that is to be informed of the results of the assay?

A. This sheet of paper doesn't inform us of that.

Q. All right.

A. This sheet of paper directs the people who takes these reports to the ward to which these reports should be taken.

Q. All right. So, it is intended to identify the ward that is to receive the biochemistry printout, the computer printout?

A. That is correct, yes.

Q. Thank you, Doctor.

A. You see, these are produced at 0339 hours, this particular one, for example. So, the majority of people in biochemistry are, you know...

Q. Not there?

A. No.

Q. All right. Doctor, as well as is obvious we can see from the left, the column on the left hand side of the page a number of categories for information. Once again we see an entry for date. We have been interpreting that information to be the date upon which the sample



H15

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was taken. Is that correct?

3

A. Yes.

4

Q. Similarly the hour of collection.

5

Again, we have been interpreting that to mean the

6

hour or the time the hour at which the sample was

7

actually collected.

8

A. The hour indicated to us on
the sample requisition that we received.

9

Q. All right, and indicating the

10

hour at which the sample was taken.

11

A. Yes.

12

Q. All righy. Similarly, the

13

next column is specimen type, and we see minor

14

variations here from the information that is set out

15

in the digoxin books, but reading across where we

16

see the letters ART, do we correctly take it that

17

that refers to a sample from an artery?

18

A. Yes.

19

Q. And where we see VEN, it is
a sample from a vein?

20

A. Correct.

21

Q. All right. And when we see O,

22

does it have the same meaning as it does in your

23

digoxin book that you have described?

24

A. Yes.

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Q. All right. Then similarly, Doctor, the next column of information appears to be volume weight and then millilitres per gram. Can you help us as to what information was intended to be set out there?

A. Yes. If any of these samples had been a urine sample then a 24 hour collection or another collection of known volume, the volume would be stated in this particular case and in this particular line.

Q. Does it apply at all to digoxin?

A. No.

Q. All right. The next column, Doctor, Duration, Day, Hour, can you tell us what is intended to be set out there?

A. That again is for generally a urine collection or possibly a stool collection; the duration of that collection. So, for example, there might be 2,400 mls in one column and just beneath that it may say 24 hours.

Q. All right.

A. So, it would --

Q. I'm sorry?

A. I'm sorry, yes.



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H17

Q. All right. Once again, Doctor,
I take it it has no application to digoxin?

A. No.

Q. All right. And then we come
to the specimen numbers and we have been reading
that information as simply being the specimen number
that was ascribed to any particular sample and that
you have told us is originally drawn from the
requisition form that happens to be filled out?

A. That is correct.

Q. All right. And those numbers
should correspond to the sample numbers indicated
in your digoxin books for any particular sample?

A. Yes.

Q. All right. And then, Doctor,
we see the results of various assays set out, the
category of which type of assay was conducted and
then the results beside it. Can you tell me, in any
given case, Doctor, for example, if you look at the
sample that was taken on March 11th, 1981 at 4:15
in the afternoon - do you see that?

A. Yes.

Q. From an artery?

A. Yes.

Q. That is Sample No. JO5428.



Ellis, dr.ex.
(Cronk)

H18

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A. That's correct.

Q. If we read down in that column, Doctor, does it mean that all of the assays which are shown to have been conducted and all of the results that are reported were taken and made in respect of that particular sample?

A. Yes.

Q. All right. Then, Doctor, we see in a number of cases again the letters NSQ. I take it that has the same meaning as it does in your digoxin books, not sufficient quantity for sampling?

A. That's correct.

Q. All right. In some situations, Doctor, we see a footnote. I draw your attention for example to the digoxin level which is reported under the column March 12th, 1981 and we see an asterisk and then the sign for greater than 10 and then underneath that a footnote, it says "See E". If we look to E below it shows that there was an insufficient quantity of the sample for further dilution. Can you help me, Doctor, when we see footnotes on those forms, do those footnotes refer to the sample result that is recorded immediately above the footnote, as appears to be the case with



H19

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this one?

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A. Yes, I believe in general that

4

is the case.

5

Q. All right.

6

A. Unless there is an overriding

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comment which will apply to all tests in that

8

particular sample.

9

Q. All right. And we see as well,

10

Doctor, in this particular case an asterisk and,
as I said, a greater than 10 nanograms indication?

11

A. Yes.

12

Q. And at the bottom of the page

13

in the left hand side we see results flagged, and

14

asterisks were reported today. Can you tell me,

15

Doctor, what the significance is in any case where
an asterisk appears beside a particular level?

16

A. It means that this particular

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sheet of paper, this particular report is the

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first one after which that particular result has

19

been reported.

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EMT/cr

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Q. I understand that, Doctor.

Are you saying then when an asterisk appears it means it is the first time that that result has been reported in writing on a clinical chemistry form?

A. It is the first time according to the computer that it has produced a report. A printed report on that particular result.

Q. Right. What then, Doctor, do the words at the bottom on the left mean when it says "Results flagged with an asterisk were reported today"?

A. It means that on the 14th of March generally speaking the first print-out of the results of the 12th of March, that particular sample, was being reported today.

Q. Does that mean then, Doctor, that is essentially an indication from the computer that the very first time that that level of greater than 10 was being reported in one of these reports was on this report dated March 14th?

A. In general, yes.

The object of this is to indicate to the person looking at this report, to draw their attention to particular items of new information.



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The result of the pH on the 11th of March has been reported on a computer print-out previously, and that is ---

Q. And that is why there is no asterisk?

A. And that is why there is no asterisk, yes.

THE COMMISSIONER: I am sorry, where is that? The pH was 7.31?

MS. CRONK: Yes.

THE WITNESS: Yes. There is no asterisk with that individual result simply because as far as the computer is concerned it has produced a report previously which contained that information.

MS. CRONK: Q. I take it then, Doctor, that the indication ---

THE COMMISSIONER: Sorry, Miss Cronk, I just don't understand this at all because surely...

MS. CRONK: Perhaps I can assist, Mr. Commissioner?

THE COMMISSIONER: Yes. All right.

MS. CRONK: Q. These reports, Doctor, are cumulative, are they not?

A. These are cumulative, yes.

Q. And I take it on a given day



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once the information is available in the computer
the results that have been fed into the computer will
be printed out on one of these forms?

A. Yes.

Q. And the computer will as well
provide any other levels in the same category, for
example, digoxin, if there was a level freshly fed
into the computer, if I can put it that way?

A. Yes.

Q. In time for it to show up
on the March 14th print-out; it might as well show
a digoxin level for March 11 if the computer knew
about that one?

A. Yes.

Q. All right. The two would be
shown?

A. Yes.

THE COMMISSIONER: You see if we turn
back a page and see that on page 82 we will see that
those figures were all reported.

THE WITNESS: Yes. This page is the
first written report of all these results. The first
opportunity that the computer had to report the
results of the 11th, that were taken on the 11th of
March, was the following day.



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MS. CRONK: Q. And that is indicated by the computer for computer purposes by the affixing of an asterisk?

A. Yes.

Q. So where we see one on page 82 beside each of those results it means the very first time the computer has produced a written report showing those results?

A. Yes. A printed report.

Q. Now hypothetically, Doctor, but still with page 82, (that print-out was dated March 12th) if the very next day March 13th the computer was asked to print out another report ---

A. Yes.

Q. Right? And because the results are cumulative, those results would show up again I take it?

A. Yes.

THE COMMISSIONER: But without an asterisk?

MS. CRONK: Q. They would be without an asterisk because they had been reported previously?

A. Yes.

THE COMMISSIONER: And if we look at page 81 that is exactly what we find.



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THE WITNESS: Yes.

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MS. CRONK: Q. Do I have that
correctly, Doctor?

5

6

A. They would be produced on the
next occasion without the asterisk.

7

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Q. I take it then, Doctor, when
these reports indicate with an asterisk and with a
footnote at the bottom, "Results flagged with an
asterisk were reported today", that does not refer
in any way to whatever oral reporting of the result
may have taken place?

12

A. That is correct.

13

Q. All right. Thank you, Doctor.

14

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A. Can I just say in addition
that many of these patients have lots and lots and
lots of results, and the object of the cumulative
report is to produce on one or two sheets of paper,
the minimum of paper, all the results that the doctor
may wish to have recourse to.

19

20

21

What this means that if you receive
a cumulative report today you should really throw
away the cumulative report that you got yesterday
because that information ---

22

Q. Is now ---

23

24

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A. - is now repeated and is



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outdated.

3

Q. Yes.

4

A. And the page numbers will

5

change. In fact it is brand new information coming

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along and it has not been able to get on to one page,

7

then the page number at the top will be updated to

8

page 2 which means that page 1 is full.

9

Q. I see.

10

A. So that the case record right

11

at the end of everything should have all the

12

information in there, but it shouldn't really have

13

the information that has been produced already that
is on a dated print-out.

14

Q. The object is to simply

15

keep full information in respect of all levels that

16

were recorded but to keep it in as compact an amount
of paper and recording forms as is possible?

17

A. That is correct. That is

18

why I am a little surprised to see page 1 here, an

19

old version of page 1 which has been updated

20

subsequently. That in theory should have been

21

thrown away.

22

Q. Right. I see. Thrown away,

taken off the medical chart entirely?

23

A. Taken off the medical chart.

24

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Q. Doctor, as I understand ---

3

A. There is only one overriding

4

occasion when an asterisk may appear on the computer
sheet, and that may not be the first occasion that

5

a printed report has been produced for that particular

6

result. This is if we need to go into the computer

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at some stage and adjust a result or add information

8

to that and produce a print-out on that particular

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occasion. So you cannot say for sure that if some-

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thing has a date - supposing we had to produce a

11

page with additional information on (I was thinking

12

very much after this date) then - sorry, I take

that back. I am getting lost.

13

Q. All right. .Well, Doctor,

14

perhaps if your thoughts clarify on that you can

15

bring it to our attention later on this morning.

16

A. Okay.

17

Q. Dealing with the reporting of

18

any particular digoxin assay result, as I understood

19

your evidence when you previously testified you told

20

us that the results of any particular assay were

21

reported orally to the ward or to the department

22

within the Hospital that had originally requested

the assay. Do I have that correctly?

23

A. Reported?

24

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Q. Orally that very day.

3

A. By telephone, yes.

4

Q. By telephone?

5

A. Yes.

8

6

Q. And whose responsibility was

7

it, Doctor, internal to your laboratory to see that

8

those results were reported by telephone on the day

9

that the assay was run and was complete?

10

A. This was the technologist's

responsibility to do that.

11

Q. And was that a matter of

uniform and regular practice ---

12

A. Yes.

13

Q. - in your laboratory?

14

A. Yes, it was.

15

Q. And that was the case in the

16

period from July 1980 to March 1981?

17

A. Yes.

18

Q. All right.

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A. When you indicate that was

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the policy in relation to wards which was the originator

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of most of our requests, simply so that that

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information was available for the appropriate treat-

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ment of the patient on the next occasion when digoxin

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perhaps should have been given. Okay? In other words

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it was for therapeutic reasons.

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Q. I can understand why, what the reasons might be for requiring those results to be reported by telephone.

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A. Yes.

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Q. And you have just addressed some of those issues. But I take it in respect of the duty or responsibility to report them by telephone, as you understood it that was the normal routine in the lab and that happened on a daily basis with respect to any assay results?

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A. Yes.

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Q. Were all assay results reported by telephone on a daily basis, Doctor, or only those, to use your language a few moments ago, which suggested some abnormality, some irregularity in the reading?

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A. No, all results were reported by telephone.

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Q. All right. And if they were not reported by telephone on a daily basis would you consider that unusual?

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A. Yes.

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Q. Doctor, in terms of the written print-out which also contains the results

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of the digoxin assay, in your experience how long after completion of the assay would these forms be generated, would the first form be generated disclosing that result?

A. How long after the assay?

Q. Yes.

A. Usually on the next day.

Q. All right.

A. The next available print-out, yes, which is usually the next day.

Q. I took it from what you said earlier that it was not actually the responsibility of your department to generate the printed version of these print-outs, and then to see in fact that they were distributed. It was not part of biochemistry's responsibility?

A. Well, this was part of biochemistry's but not part of my section or my technologist's responsibility.

Q. All right. Did you or did any technicians who work under your supervision during the time period that we are concerned with have any involvement at all in seeing that these written print-outs, computer print-outs, were distributed to the ward or the person who had actually requested the assay?



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A. No, not the technologists
in my section.

Q. All right. I take it then,
Doctor, as far as your involvement and those of your
technicians was concerned, after the report had been
telephoned to the ward or to the doctor who had
ordered the assay, at that stage your involvement
was completed in terms of the reporting of the
result?

A. It was then the responsibility
to take the digoxin work book to the main part of the
chemistry laboratory so that the key punch people
could enter the results into the computer.

Q. And after that the involvement
was complete?

A. Yes.

Q. Doctor, could you turn again
in the Pacsai chart briefly to page 91.

Do you have that, Doctor?

A. Page 91? Yes.

Q. Doctor, we see here another
form of clinical chemistry cumulative report, and
it appears to be identical to the other format which
we observed on page 83 of the record except for the
entries across the top. There is an autopsy number



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instead of the patient name, and there is something called REG number as opposed to an admission number, and as well if we look to the last column we see the word "dest" which we have taken to mean destination as opposed to the indication of ward.

Can you help us at all, Doctor, as to what the significance or what the purpose of the information in the last category on that page was on these forms?

A. Well, the destination is to the Pathology Department.

Q. Right. And in this particular case it happened to be Pathology because that is the indication, but my question is, perhaps properly put, is the information in that column as you understood it intended to identify the department within the Hospital who was to receive the assay results?

A. Yes.

Q. All right, thank you, Doctor.

Doctor, I would like to turn now to the specific digoxin assays that you either performed or supervised in the Hospital dealing first with blood samples that were received in the laboratory.

May we turn to the case of Janice Estrella?



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We know, Doctor, that a number of blood samples were assayed during the life of Janice Estrella and as well after her death for digoxin. Were those assays conducted in your laboratory under your supervision?

A. Yes.

Q. Doctor, could you turn, say, to an exhibit that you have, Exhibit 32B, to Tab 46, if you would. The thick one that I believe you have there.

A. Okay.

Q. Tab 46.

A. Yes.

Q. Page 167. Very near to the back of that tab, Doctor. Do you have it, Doctor?

A. Yes.

Q. Doctor, you see at the bottom of page 167 under the date January 7th, 1981, an entry with respect to Sample No. ZH56908, and on the basis of your evidence earlier this morning I take it we should properly be reading those entries to mean that that sample was taken at 8:30 a.m. on the 7th of January, 1981; that it was accorded Sample No. ZH56908 and that the sample came from an artery and that a level was achieved of greater than 5 nanograms.



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Am I reading that correctly?

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A. Yes.

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Q. All right. Doctor, in respect of that particular sample as I understand it the sample was then further diluted and re-assayed by virtue of the fact that when it was first assayed on the 7th of January it was done neat without dilution. Do I have that correctly?

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A. Yes.

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Q. Right. The first time it was run it was neat, and it was simply off the maximum which could be recorded on the RIA methodology without further dilution.

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Do I have that correctly?

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A. Correct, yes.

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Q. And then if we turn to page 168, the next page, we see the entries for the assays that were conducted on January 8th, 1981, and we see, do we not, that the same sample was diluted and re-assayed on that day with the result this time of greater than 9.4 nanograms.

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Am I reading that correctly?

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A. Yes.

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Q. Doctor, there are a number of handwritten entries beside the name of the patient



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Janice Estrella we have had difficulty reading. Right above the name Janice, can you see them?

A. Yes.

Q. Do you know what those entries refer to?

A. These look like entries by my technologist to say that one sample - one tube was analysed at 25 microlitres instead of the usual, instead of the usual 50. It is not really very clear, actually, is it?

It looks almost as though there were two single 25 microlitres.

Q. For a total of 50 microlitres?

If there were two, Doctor, at 25 the total would be 50 which is the normal amount you told us previously was used for the assay. Is that correct?

A. Yes. 50 microlitres is the usual amount.

Q. And if there were two here at 25 ---

A. Right.

Q. A combination in total you had the amount that was normally used?

A. Yes.



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Q. If that is what the entries

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mean?

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A. Yes, that is correct, but you

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are implying that it went into the same tube. I am

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saying that this notation indicates that there was
relatively little sample left, indicates to me ---

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Q. I see.

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A. - there was relatively little

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sample left, of the order of 50 or 60 microlitres,

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and that it was necessary for the technologists to
use 25 microlitres.

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Q. And that would be run in

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duplicate?

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A. If there is sufficient material

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to do, yes.

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Q. And is that what the two

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entries of 25 would mean?

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A. It is a little bit unusual

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for them to note something twice in that way.

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Q. So I take it we can't be sure

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what that does refer to?

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A. No, we can't. It looks almost

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as though they were going to do 25 microlitres once

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and then they attempted to get a second amount, and

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then noted that second amount.

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Q. All right.

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A. But I can't be sure.

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Q. And, Doctor, if we look again

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at the result that is reported, the greater than

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9.4, we see again a handwritten entry above it which
I have been reading to be diluted times two.

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A. Yes.

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Q. Greater than 4.7. Am I reading

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that correctly?

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A. Yes.

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Q. And, Doctor, we know that the

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first time it was assayed the result was reported as
greater than 5. We saw that on the previous page.

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A. Yes.

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Q. And now we see that when the

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sample is diluted times two we are getting a result

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of 9.4 and the technician has indicated that the

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mathematical way of computing the result of the

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dilution is to multiply a greater than 4.7 level
times two.

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Do I have that correctly?

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A. Yes.

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Q. All right. Are we then

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correctly to take it, Doctor, that the greater than

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5 level reported the previous day or recorded in

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the book the previous day, is in fact the same as if it had been reported at greater than 4.7? The two are synonomous in this sense that they both mean that when the sample was assayed at that time it was over the maximum which could be detected on the RIA methodology and had to be diluted further in order to get a result?

A. Yes.

Q. So in that sense the greater than 4.7 could just as easily have been described as it was in this case as greater than 5?

A. Yes. There was a changeover period when we decided that the best value we could assign to our highest standard was not 5 as claimed by the manufacturers but a value of 4.8 or 4.7. 4.7 around this time.

Q. Had that changeover taken place by January 8th, 1981?

A. Without reading through this book and seeing what we had been reporting I can't tell you.

Q. All right.

A. But it looks as though there is a little bit of confusion in my staff's mind as to whether they should be reporting greater than 5



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or greater than 4.7.

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Q. Do I take it then, Doctor,
that in terms of how you report the first assay
result if it is off the maximum, if greater than
4.7 is to be regarded in that context as the same
as greater than 5, that this result on the 8th of
January of greater than 9.4 could just as
appropriately be regarded by us as greater than 10?

It simply means that when it was diluted
times two and re-assayed the result once again was
off the maximum that could be measured by the RIA
method and would require further dilution for a
fixed reading to be obtained?

A. Yes.

Q. Is that correct?

A. It would require further
dilution to get a more accurate answer greater than
9.4.

Q. Right. And in that context
the greater than 9.4 could as easily have been
described as greater than 10?

A. Well, our best estimate of
this result was that our top standard was 4.7,
and therefore we said that it is greater than 9.4.

Q. Well, I have ---

A. That was our top standard.



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Q There may be nothing that turns on it Doctor, but I want to be clear about it, and I am having some difficulty with it, because the previous day the result was reported at greater than 5.

A Yes.

Q And on a dilution of 2, if it was off the top of the measurement which the RIA method was capable of providing by virtue of simple multiplication means the results are greater than 10, is that correct?

A Yes.

Q Doctor, from the review that we have conducted of the medical record, it is apparent that the level of greater than 5 that was achieved on January the 7th was reported by a Biochemistry or Clinical Chemistry printout form dated January 14th, 1981, and that appears at page 159 of Janice Estrella's medical records. I should tell you thought that on my review of the medical record it does not appear there is a Clinical Chemistry printout showing the results of a level of greater than 9.4, or a level of greater than 10. Can you help me as to why that would be the case?

A Well, I can tell you - I am sorry, which page are we on?



J.2

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Q. Doctor, I am sorry, you don't even have to look at the tab that is before you. I am suggesting to you that on the first assay of this sample the result was greater than 5?

A. And that result was produced.

Q. In a Clinical Chemistry printout form which is contained in the medical record of Janice Estrella?

A. Yes.

Q. Then the very next day it is diluted and it is re-assayed and we know the result this time is again off the top of the measurement of which the method is capable and it was recorded in the digoxin book as greater than 9.4. I am suggesting to you that based on my review of the medical record that greater than 9.4 or greater than 10 result does not appear to have been reported in the Clinical Chemistry form to the ward?

A. Yes.

Q. My question to you is, if that be so, can you help me as to why that would be the case?

A. I can tell you the mechanism by which that failed to be reported to the ward.

Q. All right.

A. Looking at this photocopy on



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page 168 you will see that the registration number,
page 568, I am sorry, page 56908, relating to that
sample that was greater than 9.4, has been crossed out.

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Q. And why is that, Doctor?

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A. We would cross out information
if we didn't wish the reporting people to attempt to
enter that into the computer. In other words, if we
knew that it had been reported already and we - not
for any reason of cover-up or anything like that; if
we didn't wish a report to be produced we would cross
through that number.

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Q. Why in this - I am sorry, Doctor?

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A. That would prevent the person who
was trying to enter all these results from going to
the computer, entering this patient ID specimen, the
specimen identification information and the computer
telling her, hey, I have a result before of greater
than 5, what do you want me to do? Then they would
be faced with a decision as to whether they should
really enter it or whether they shouldn't, and then
they would have to leave notes for their supervisor
for the next day and they would have to come and see
us, okay. So that was one reason.

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The second reason is, if you look down
on Thursday, the 8th, the area that we are looking at



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when this dilution is being done, you will see that we also had a sample dated the 8th, in other words we have a fresh sample. Okay. So in relation to what you do with the digoxin result, or what the doctor does when he gets it back, we had two days' information which makes yesterday's information less relevant than it would have been yesterday. Okay. So yesterday's information as reported by telephone yesterday said, this result is high and the implication is stop the digoxin. On the subsequent day a fresh sample occurs and that is still high, in other words the digoxin value is going down, but it is still above our upper limit. The indications are still stop the digoxin, and there is no difference in reporting greater than 9.4 or greater than 5.

Q. I will come to the second sample in just a moment, Doctor. In terms of the reporting of the result of greater than 9.4, I take it then that the greater than 5 result which was achieved on January the 7th, to the best of your knowledge, was reported by telephone that very day?

A. Yes.

Q. Do you know whether the result of greater than 9.4 was reported by telephone on January the 8th?



J.5

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A. I don't know.

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Q. Having regard to the fact that it doesn't appear that there is a Clinical Chemistry printout in written form reporting the result; and having regard to the fact it is crossed out in your book, would you agree with me that it is likely it wasn't reported by telephone that day?

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A. It is likely, yes.

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The other thing I would say is, as I have indicated before occasionally immunoassays give erroneous results and very rarely, in individual patients for no immediately obvious reason, very, very unusual this is, but on occasion when you take those samples and you dilute them down, then when you do the dilution you get a totally haywire result.

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In other words, the specific instance that I am referring to as I have alluded to before is for thyroid stimulating hormones and we have had I think two patients in a period of three or four years where we had reported a result, we had obtained a result of greater than 60 and on dilution of that sample that result of greater than 60 could not be substantiated.

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Q. Was there any suggestion in this case, Doctor, that the result of diluting the



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Estrella sample times two had the effect of producing
an abnormal or unreliable level?

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A. No, I think the result that we
produced the previous day that said, hey, it is
greater than 4.7 or 5, was confirmed by this dilution
that it was in fact greater.

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Q. High?

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A. Yes.

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Q. And in terms of the oral
reporting of this level, if it be so that it was not
in fact reported, I take that to be an exception to
the general rule, the norm which applied, and that is
every result, not just results that were deemed to be
significant, but every result had to be reported by
telephone on a daily basis, this would be an
exception to that?

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A. Yes.

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Q. Is that correct?

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A. Yes.

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Q. Doctor, beside the name Janice
Estrella as well, on that sample there is an asterisk,
and if we look to the bottom right-hand side of the
page the entries of January 12th, there is another
asterisk. As I read it it says: Used new standards
and controls. Can you help me, does that have any

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significance in terms of the assay that was conducted
on January the 8th on this sample?

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A. No, let me see?

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Q. Do you see where I am referring to?

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A. Yes.

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Q. Does that have any significance
in terms of this sample?

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A. I don't know, I don't know who
wrote that.

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Q. Do you know what the reference
means?

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A. They strongly suggest that
somebody was changing standards and controls at around
this particular time period and when they exactly
wrote that I don't know. It would confirm this view
that on one day we were reporting greater than 5 and
on another day we were reporting greater than 4.7.

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Q. I am sorry, are you saying -
well, with reference to the other sample you were
reporting greater than 4.7?

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A. Yes. But on the --

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Q. Yes, I understand that.

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A. But on the 7th we reported
greater than 5, that if this notation is correct that
you have just drawn my attention to, which has an



J.8

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asterisk, then that could well be why we reported greater than - 5 was our upper limit on that particular occasion.

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Q. My curiosity arose, Doctor, because the asterisk as it happens appears only beside the name Janice Estrella on January the 8th.

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A. Yes.

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Q. I didn't know whether then to infer that all the assays done on January the 8th were run on new standards and controls, or whether it was merely the sample from Janice Estrella, do you know?

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A. I don't know. This looks almost as though somebody was putting it in very much in retrospect, doesn't it?

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THE COMMISSIONER: Janice Estrella is the only one who is over the limit of 4.7 or 5 as the case may be?

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THE WITNESS: Yes.

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MS. CRONK: On two different samples, sir, but the second sample doesn't appear to have been run on January the 8th on new standards and controls, there is another sample reported at greater than 4.7 on January the 8th.

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THE COMMISSIONER: That is, the 4.7 is the new standard, isn't it?

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MS. CRONK: I am sorry, we had better clarify that, Mr. Commissioner, and perhaps it is misleading.

Q. I took that reference to the new standards and controls, Doctor, not to refer in any way to the maximum measurement of the scale but rather to refer to the five standards which you have told us when you testified previously were used in the actual run on a radioimmunoassay test to assist in achieving the results. In other words, the standards are known amounts of digoxin that are provided to you by Antibodies Inc.?

A. No.

Q. I am sorry.

A. Standards are vials of standard material provided to us by Corning.

Q. And that is what the reference refers to, it doesn't refer to the maximum measurement of the RIA measure, it refers to the standards that are physically used, the vials of digoxin materials?

A. Yes.

Q. That are physically used in the test?

A. Right. But they are prepared by additional water to a freeze dried material.



J.10

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Q. All right.

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A. And that freeze dried material will last for a finite length of time, be it days or weeks.

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Q. And when it runs out --

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A. When it runs out you have to use new standards.

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Q. Right. My only question to you, Doctor, can you help us, and perhaps you can't, as to why, as it appears, new standards were only used on Janice Estrella on January the 8th, and only then on one of two samples that were available from Janice Estrella?

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A. No, that would not apply. If new standards were used on January the 8th they would apply to all subsequent samples, not just the individual patient, that is not the indication there.

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Q. All right, thank you.

A. It may have been that in retrospect we looked at this page in respect specifically of Estrella looking for something unusual.

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A. But on the other hand there is a space at the bottom so it looks as though it was put in after the Monday, doesn't it?



J.11

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Q. Insofar as you are aware, Doctor,
I take it then that that sample was not treated any
differently?

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A. No.

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MR. HUNT: I just have a question and
maybe my friend is getting to it. I assume in the
book these are separate pages, because they are
numbered separately, 168, 169 and the asterisk appears
on the bottom of Monday, January the 12th. Has it
been clearly indicated that that asterisk at the
bottom on Monday, January the 12th, relates back to
an asterisk on another page two days before that?

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MS. CRONK: Fair enough.

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Q. Doctor, can you help Mr. Hunt
with that? I must say I assume that to be the case,
and Mr. Hunt is quite correct, it is two separate pages.

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A. Yes. I agree, I recognize that.
Without seeing the original and seeing whether there
are any asterisks anywhere else, there don't appear
to be. My presumption is that some time after Monday
the 12th of January somebody wrote this comment in
relation to new standards and controls having been
used. Okay. My guess is that there may have been
some discussion about whether we should be reporting
greater than 5 and greater than 4.7, and perhaps



J.12

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somebody wrote it in relation to that.

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Q. Well, I am sorry, Doctor, I don't want to complicate it any more than perhaps it already has been. I have as it happens the original here for January the 8th, the digoxin book, and the entries for January the 9th appear in part on the same page, and the entries for January the 12th on the next immediately facing page. Do you know, and perhaps you don't, do you know what the significance of that entry is for new standards and controls used?

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A. No.

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Q. Do you know what the significance is of the asterisk beside Janice Estrella's name on the entries for January the 8th?

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A. No.

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Q. Thank you.

A. The only thing I can say that the ink is the same colour, that ink there, whereas in the photocopy it looks as though this person wrote that asterisk.

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Q. They appear to relate?

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A. Yes.

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Q. Doctor, may we turn then to the next sample which was assayed on January the 8th. You have indicated previously that that was a fresher



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sample, it was a sample that was provided to the lab on January the 8th. If we are reading your entries correctly that was a sample drawn at 10 a.m. on January the 8th, Sample No. H56921, drawn from a vein, and it resulted in a level of greater than 4.7, am I reading that correctly?

A. Yes.

Q. Once again it came from Ward 4A.

A. That is correct.

Q. And that sample as I understand it, Doctor, was again repeated the next day at a dilution of times two, and we see that entry under Friday, January the 9th, and that result at that time was 7.8 nanograms. Do you see that?

A. Yes.

Q. Doctor, that entry as well is crossed out and the word "check" appears beside the level of 7.8 and that is crossed out as well. Can you tell me what significance, if any, there is to the fact that those entries are crossed out?

A. It suggests to me that the technologist wrote "check" because it was his understanding that this assay was to check on the previous day's assay, not that it was to be reported in the usual way of reporting assays. Okay.



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At some stage after this we would report, whatever number we got eventually, we would report that number. Okay. Prior to this point there were, we would quite often report greater than 5 without going any further. That indicated to the floors that they should stop giving digoxin and that was all the information that they needed.

Q. In those circumstances then I take it that the ward might or might not be informed of the fact that you had further assayed a particular sample on dilution and obtained another result?

A. That is correct.

Q. And in this case again the 7.8 level appears to have been crossed out?

A. Yes.

Q. Would you agree with me on the basis of what you have just said that it is unlikely that that result was reported orally that day?

A. Very unlikely, yes.

Q. But it is likely that the greater than 4.7 level was reported on that sample the day previously?

A. Yes, that would have been reported, yes. Sure, in fact there is also a tick by the side of it.



J.15

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Q. The tick means that it was reported?

4

5

A. That would mean that it went into the computer.

6

7

Q. Should there then be, Doctor, a tick beside all of these levels if they were fed into the computer?

8

9

A. People are relatively inconsistent.

10

11

Q. It can mean that if it is there, but it doesn't mean it wasn't reported if it is not there?

12

13

A. That is correct.

14

15

16

17

Q. Doctor, can we turn then to the next sample which also appears to have appeared in the Biochemistry laboratory on January the 9th, and that is Sample H57574, and if I am reading those entries correctly that is a sample that was taken at 3:30 p.m. on January the 8th on Ward 4A from an artery?

18

19

A. Yes.

20

21

Q. And there was insufficient quantity of sample to permit an assay on that particular sample?

22

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A. That is correct.

Q. Doctor, the next sample then the same day, is Sample No. H56924, and that appears



J.16

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to have been taken on the ward on January the 9th, 1981
at 9:30 a.m. and this time from a vein; do you see
that?

A. Yes.

THE COMMISSIONER: I am sorry, 9:30?

MS. CRONK: At the top of page 169, sir.

THE COMMISSIONER: Oh, yes, I see.

All right.

MS. CRONK: Q. That is taken the next
day, Doctor, on January the 9th, and it is assayed on
that same day, January the 9th, and it resulted in a
level of 4.7?

A. Yes.

THE COMMISSIONER: I wonder if we
could, while we are just looking at it, hour of
collection. So I can get these hours straight, you
have got 9:30 on page 169 of the Preliminary Inquiry
exhibit, and you say at 159 of Janice Estrella's
Exhibit 91, it seems to be 9 o'clock, did I miss
something on that? Where do these hours come from?
What are the hours in your book, what do they mean?

THE WITNESS: The hours in the book
should be the hours on the sample requisition, yes.

THE COMMISSIONER: Where would they
have gotten this figure of 0900?



J.17

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THE WITNESS: On the computer printout?

3

THE COMMISSIONER: Yes.

4

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THE WITNESS: I can't explain that discrepancy, they should be the same.

6

7

THE COMMISSIONER: They should be the same?

8

THE WITNESS: Yes.

9

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MS. CRONK: To assist you, Mr. Commissioner, I have not seen a requisition form that applies to this particular sample, so I can't assist you as to what time might have been indicated on it as the hour for collection.

13

14

THE COMMISSIONER: It might conceivably be a human error if somebody were to transform from one thing to the computer.

15

16

THE WITNESS: Yes.

17

THE COMMISSIONER: And they put the wrong hour down.

18

19

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21

THE WITNESS: It is possible. Occasionally samples are, not very often, but occasionally labels are stuck on blood tubes or syringes that come in ---

22

THE COMMISSIONER: At any rate it is either 9 or 9:30. Yes, I am sorry, Miss Cronk.

23

24

MS. CRONK: Q. That sample, Doctor,

25



J.18

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2

was clearly taken at either 9 or 9:30 on the 9th of
January before the child died?

3

4

A. Yes, on the Friday.

5

6

7

Q. And clearly therefore an ante-
mortem blood sample having been drawn from a vein,
would you agree with that? I am sorry, it is clearly
an antemortem sample drawn from a vein?

8

9

A. Yes, I would presume that. I
don't know exactly when this child died.

10

11

Q. I am sorry, Doctor. The child
died on January the 11th, 1981.

12

A. Okay, right.

13

14

Q. If that be so, it is clearly
an antemortem blood sample, do you agree?

15

A. Yes.

16

17

18

Q. And that sample, Doctor, appears
as well to have been diluted and re-assayed on the
very same day, do you see that entry immediately below
the first?

19

A. Yes.

20

21

Q. I am having difficulty reading
the number, but I take it to be a times two dilution?

22

A. Yes.

23

Q. And the reading this time is
expressed to be 5?

24

25



J.19

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A. Yes.

3

Q. 5 nanograms?

4

A. Yes.

5

Q. In terms of the significance

6

attached to those two levels in your laboratory, would

7

I be correct in concluding that a level of 4.7 and a

8

level of 5 as they are close to the maximum which the

9

IRA method is capable of measuring would be treated

10

as virtually the same result?

A. Yes.

11

Q. And once again that particular

12

entry is crossed out, Doctor, and would we correctly

13

then regard that as not the level of 5, as not having

14

been reported by telephone that day to the ward, but

15

rather the level of 4.7 that would have been reported

16

orally?

A. Yes, that is correct. Hopefully

17

on the computer printout that result had gone up too.

18

Q. As it happens, Doctor, with

19

respect to a number of these assays, they were run on

20

January the 8th and on January the 9th as we have

21

seen, yet the earliest printout, the earliest Clinical

22

Chemistry printout that appears in the medical chart

23

of Janice Estrella is dated January the 14th, that is

24

a delay of some five or six days between the day

25



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Ellis, dr.ex.
(Cronk)

732

J.20

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that the assays are run and the day that the results

3

appear to be reported. Can you help me as to why

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that might be the case, reported in writing, or do you

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know?

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A. I don't know. Was there a flag to indicate that that was the first time that digoxin result was being reported?

Q. I am sorry, in fairness, Doctor, there is not.

A. Okay.

Q. So, do we correctly assume therefore that there had been an earlier printout disclosing that result?

A. Yes, which was updated at some subsequent time.

MS. CRONK: All right, thank you, Doctor.

Mr. Commissioner, I am about to move to the postmortem samples, would this be an appropriate time to break?

THE COMMISSIONER: All right. Then we will rise now until 2:30.

--- Luncheon adjournment.

-



AA/BM/ak

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---Upon resuming at 2:30 p.m.

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THE COMMISSIONER: Yes, Ms. Cronk.

4

MS. CRONK: Q. Dr. Ellis, just

5

before we broke at lunch we had finished reviewing
the antemortem blood samples upon which digoxin assays
were conducted in your lab. I would ask you to turn
back again if you would to Exhibit 32B, Tab 46,
Doctor, page 169. Do you have that, Doctor?

6

7

A. Yes.

8

Q. All right. Doctor, under the

9

entries for January 12th, 1981 on the right hand
side of the page, page 169, we see that yet another
sample was delivered to the lab for digoxin assay
purposes, it is Sample No. G89241. If I am reading
your entries correctly the sample came from the
Pathology Department, it was taken on the 1st of
January at an unknown time on the basis of the
entries in your book and on the first assay without
dilution it was required that the assay be repeated
because no fixed level could be obtained. Am I
reading that correctly?

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11

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A. Yes.

20

Q. All right. Doctor, we see

21

again the initial O beside that particular specimen.
I take that to mean that at the time the requisition

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AA2

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form was provided the technologist in your lab who was checking the requisition form didn't know whether the sample was from a vein, from an artery or what the sample type in fact was and hence the letter O was indicated beside the sample.

7

A. Yes.

8

9

10

Q. All right. Doctor, we see in handwriting as well beside the name Janice Estrella the words "postmortem possibly diluted specimen". Do you know whose handwriting that is?

11

A. No.

12

Q. All right.

13

THE COMMISSIONER: I'm sorry?

14

15

MS. CRONK: Right beside the name, Mr. Commissioner, in small handwriting.

16

17

THE COMMISSIONER: 169? Oh, yes, I see it, yes, you are quite right.

18

19

MS. CRONK: Q. Doctor, do you know what that reference refers to?

20

A. The possibly diluted specimen?

21

22

23

24

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Q. Yes.

A. I understand there was some concern about the quality of this particular sample that was received from pathology.

Q. All right. In your experience,



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Doctor, prior to the case of Janice Estrella, had you ever before received a sample from the Pathology Department for the purposes of digoxin assay, to the best of your recollection?

6

7

A. It was not our regular occurrence for us to receive samples from pathology.

8

9

Q. No, I wouldn't have thought so. But do you recall receiving one prior to this one from pathology?

10

11

12

13

A. No. But I believe that when I went back through the book, when these kind of questions were being asked, I think one had in fact come from pathology a long time before prior to this.

14

15

16

Q. All right. So, this then would have been the second sample of that kind received from the Pathology Department?

17

18

19

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21

A. As best as I can tell, yes.

22

23

24

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Q. All right. And that I take it marked this sample as being somewhat unusual in that the source from which it was obtained was the Pathology Department and presumably therefore it was an autopsy sample.

A. Well, yes.

Q. All right.

A. But it also says post mortem.



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Q. And what significance do you attach to that? Don't the words post mortem as well indicate that it is an autopsy sample?

A. Yes.

Q. Doctor, you said that you understood that handwritten reference to mean there was some question as to the quality of the sample. On what basis did you gain that impression?

A. Yes, I think I was under the impression that the sample requisition contained this information but in fact you showed me this requisition and it doesn't, or at least the copy that you have doesn't.

Q. All right.

A. I cannot remember precisely the exact way in which we happened to come to know it was possibly a diluted specimen but I know that when this sample was being discussed there was always this rider as to whether the sample quality was satisfactory.

Q. When this sample arrived at the lab for testing, Doctor, was the fact that it had been received and the fact that it was a post-mortem sample drawn to your attention?

A. During that week I think it did,



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yes. I can't say for sure that on Monday, January 12th that this was drawn to my attention specifically.

Q. You don't have any recollection one way or the other?

A. Specifically for that day, no.

Q. All right. Do you have any recollection at all, Doctor, as to when you learned that there was some question as to the quality of this sample?

A. If it wasn't on January 12th it was within a few days of that.

Q. Do you remember who told you or what led you to understand that there was some question about the quality of the sample?

A. I think in discussion with my technologist this point arose. I think that at the preliminary hearing flow sheets were prepared, large flow sheets of individual samples and these were admitted in evidence. In referring subsequently to our conversation of last week, to that flow sheet, in fact I think you will find that the flow sheet it says that the tube itself was labelled possibly diluted specimen.

Q. All right.

A. We have reason to believe that



AA6

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this sample was not a usual sample.

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Q. All right. Doctor, could you turn to Tab 53. Perhaps you could keep your finger just at that page and turn as well to Tab 53 of the same book. Do you have that?

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A. Yes.

Q. All right. That, Doctor, is a clinical chemistry requisition form bearing the same sample number as this sample number.

A. Yes.

Q. G89241. It appears to have been signed by Dr. Glenn Taylor. Were you aware, Doctor, in January of 1981 as to who Dr. Taylor was?

A. No.

Q. Did you know that he was with the Pathology Department at the Hospital?

A. Well, having seen this requisition that would be the assumption one would make but I didn't know him personally.

Q. And that assumption would be based on the fact that the requisition form indicates that the results were to be forwarded to Dr. Glenn Taylor of the Department of Pathology?

A. Yes.

Q. All right. We see, Doctor,



1
2 that under the other request section of the requisition
3 form it simply indicates digoxin levels two
4 specimens A and B. I take it we can agree, as you
5 have suggested, that there is no suggestion on the
6 face of the requisition form that any indication was
7 given by Dr. Taylor, at least on this document,
8 that there was some question as to the quality of
9 the sample, is that correct?

10 A. Yes.

11 Q. All right.

12 A. The only thing is, this is
13 the Z copy. The requisition form comes in three
14 copies.

15 Q. Yes.

16 A. The middle copy is the Z copy.
17 That is indicated by the little 'z' in the box at
18 the bottom in the centre.

19 Q. Yes.

20 A. Okay.

21 Q. And does carbon paper separate
22 the other two copies, Doctor?

23 A. Yes.

24 Q. All right. Well can we agree
25 then if there had been any handwriting on the front
face copy of the requisition form that suggested



1

2

that there was some issue about the quality of the
sample, that would likely be on the other copies?

3

4

A. That's correct.

5

Q. All right.

6

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A. The only reason I mentioned
the Z copy is that the moment this requisition comes
into the laboratory the Z copy is removed. Any
comments written by technologists would not
necessarily show on the Z copy.

8

9

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11

Q. Do you have any recollection,
Doctor, as to whether the original top copy of the
requisition form contained any comment at all?

12

13

A. No.

14

15

Q. Regarding the quality of
this sample?

16

17

A. Not that specific item, no.

18

19

20

21

Q. All right. Doctor, you have
told me that by the time the preliminary hearing
started in respect of Susan Nelles flow sheets
were prepared and I gather there was some suggestion
in those flow sheets that there was an issue over
the quality of this sample?

22

A. Yes.

23

24

25

Q. All right. But during the
year before that, in January of 1981 when this



1
2 sample was being assayed, I take it you can't help
3 us as to how you formed the impression that the
4 quality of this sample was in issue?

5 A. No.

6 Q. All right. Do you recall
7 specifically, Doctor, having any discussion with
8 any of your technologists with respect to that
9 aspect of this sample at the time it was being
10 assayed?

11 A. No.

12 Q. All right. What did you
13 understand, Doctor, the reference to possibly
14 diluted to mean? You have told me that you thought
15 there was some question about the quality of the
16 sample? Did you address your mind specifically
17 to what that might mean? How was the quality of
18 the sample in issue?

19 A. We usually receive blood
20 and blood serum and that this material contained
21 additional material and fluids additional to the
22 blood in, you know, such a way that the blood would
23 be diluted with whatever material the dilution
24 occurred with.

25 Q. Did someone tell you, Doctor,
that the sample contained materials other than blood?



1

2

A. No.

3

4

5

Q. All right. Was that something then that you deduced from the language of the handwritten note which appeared in the digoxin book?

6

A. Yes.

7

8

9

10

Q. All right. Doctor, with respect to this particular sample, after the first assay had been conducted on January 12th, do you recall checking the digoxin book and noticing that a postmortem sample had been sent for assay?

11

12

A. I'm sorry, which time are you referring to?

13

14

15

16

Q. On January 12th when the sample was first assayed, do you recall checking the digoxin book that day and noticing that a postmortem sample had come in for assay purposes?

17

18

A. I believe it was brought to my attention on that day or within the next few days.

19

20

Q. All right.

A. And I think we did further tests on this sample.

21

22

23

24

25

Q. All right. That's right, Doctor, and I will come to the further dilutions in a moment that took place. But with respect specifically to the events of January 12th, having



1
2
3 regard to the fact that you have told us that to
4 the best of your recollection only one other post-
5 mortem sample from pathology had ever been sent to
6 the lab for digoxin assay purposes, were you
7 surprised to receive at this time a sample that
8 clearly was from pathology taken at autopsy?

8 A. Not really, no.

9 Q. What did you understand,
10 Doctor, the purpose of doing a digoxin assay on a
11 postmortem sample from autopsy?

11 A. I didn't question the
12 purpose for which this was being done. I assumed
13 that the originator of the request had a reason for
14 asking us to do the analysis and we would do the
15 analysis.

16 Q. Did you contact Dr. Taylor
17 of the Pathology Department to discuss the sample?

17 A. No.

18 Q. All right. Did you contact
19 any of the involved clinicians who had been
20 involved in the care of the child to discuss this
21 sample?

22 A. No.

23 Q. All right. Doctor, as you
24 have indicated ---
25



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A. Can I say also that on Monday, March 12th, all we knew really was that the result was greater than 4.7.

5

Q. That is what the repeat means?

6

7

8

9

A. No, the repeat for this sample means that it is, okay, it is more than 4.7. It doesn't mean to say that it is 20 or it is 30 or it is 40 or 50. We have seen greater than 4.7s before, as you would appreciate.

10

11

12

13

14

Q. Well, Doctor, in respect of this sample I take it that on March 12th when the first assay was run you couldn't arrive at a level, you had to dilute it and reassay it to come up with a specific level.

15

A. Yes.

16

17

18

Q. As I understand it, Doctor, that in fact took place the following day on January the 13th, the sample was again assayed this time on a dilution, is that correct?

19

A. At which time is that, please?

20

21

22

23

24

25

Q. All right. Well, to assist you Doctor, it appears there was a photocopying error when these digoxin books were reproduced and I have had photocopies made of the entries from the digoxin books for January 13th and January 14th, 1981.



1

2

I would ask you to look at them and tell me if you
can recognize them as entries from the digoxin book?

4

A. Yes.

5

6

7

8

A. January 13th, yes.

9

10

11

Q. All right. And the result
at that time was simply the necessity for a repeat
assay, the level couldn't be determined?

12

A. No.

13

14

15

16

A. Greater than 9.7.

17

18

Q. I'm sorry, greater than 9.7,
and it had to be reassayed.

19

THE COMMISSIONER: 9.4.

20

THE WITNESS: I'm sorry.

21

22

MS. CRONK: Q. Greater than 4.7 times
2.

23

A. Okay, yes.

24

25

Q. So, it would be greater than



1

2

9.4 and it had to be reassayed?

3

A. Yes.

4

Q. All right. Then it appears,

5

Doctor, that on the very same day it was in fact

6

reassayed again, this time at a dilution of 10?

7

A. Yes.

8

Q. And at 5?

9

A. Can I just go back one stage

10

in that there were samples being analyzed there on
the previous day.

11

Q. Yes, there were, Doctor. I am

12

directing my attention however for the moment to

13

this Sample G89241.

14

A. Yes.

15

Q. All right. If you take a

16

look at the sample numbers on January 13th it

17

appears that that particular sample was diluted first

18

times 2 and assayed, then it was diluted times 5

19

and assayed again, then it was diluted times 10 and

20

assayed again, all on January 13th. Am I interpreting
those notations correctly?

21

A. Yes.

22

Q. All right. And in each case

23

the result was that the level was off the maximum

24

measurement of the test and it had to be reassayed,

25

correct?



1

2

A. Yes.

3

4

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6

Q. All right. And then we come to January 14th and the same sample was again reassayed, again at a dilution of times 10. Do you see that, Doctor?

7

A. Yes.

8

9

Q. And once again, as it was the previous day, it was off the maximum measurement of the scale and had to be repeated?

10

A. Yes.

11

12

Q. And then I would ask you, Doctor, to turn if you would ---

13

14

15

16

A. I'm sorry, I think I may have been following you a little bit. If we go to Tuesday, January 13th, Sample I, you said that that indicated it had been analyzed times 10.

17

Q. Doctor, to assist you, I am looking in the result column.

18

A. Yes.

19

Q. Where it says repeat.

20

A. Yes.

21

22

Q. And it says times 5 and times 10, does it not?

23

A. Yes.

24

25

Q. Does that not indicate that



1
2 it was diluted times 5 and then diluted times 10 and
3 assayed?

4 A. That would suggest ---

5 THE COMMISSIONER: It is conceivable
6 that that is a question mark, is it, after times 10?

7 THE WITNESS: I think that is
8 some photocopy from the next page. It looks almost
9 as though here it was done times 5 and somebody
10 decided to repeat it and they advised the person
11 next that they should repeat it times 10. You see,
12 it says repeat times 5 and just above it it says
times 10.

13 THE COMMISSIONER: Just below it.

14 MS. CRONK: Q. Just below it. Doctor,
15 I am showing you the original.

16 A. Okay.

17 Q. And beside the word repeat
18 it says times 5 and then times 10. There doesn't
appear to be a question mark beside either of those.

19 A. Oh, yes, okay.

20 Q. All right. Would you agree
21 with me that that suggests that the sample was
22 diluted on three occasions on that day, on January
23 13th, first at times 2 dilution and then at times 5
24 and then at times 10?
25



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THE COMMISSIONER: It's not times 5,
it is greater than 5, isn't it? Isn't it greater
than 5?

MS. CRONK: It is an X, sir.

THE COMMISSIONER: Well, isn't that
greater than in some circles?

MS. CRONK:Q. Well, it can mean greater
than 5 and it can also mean diluted times 5, as I
understand it. Perhaps you can help us, Doctor,
do you know how many dilutions were done that day?

A. Not offhand, no.

THE COMMISSIONER: I'm sorry, what
is it, what does the X stand for again? To me, if
you dilute it times 5 you get into some astronomical
numbers, do you not?

THE WITNESS: Yes, 25.

THE COMMISSIONER: 3 or 4 hundred,
don't you?

THE WITNESS: No, no.

MS. CRONK: No, sir, it would simply
mean that if you had a level greater than 4.7.

THE COMMISSIONER: Twice, diluted
twice.

MS. CRONK: It would be greater than
9.4.



1

2

THE COMMISSIONER: All right, let's
make it easier for me, let's make it 10. Three times
would make it 20.

5

MS. CRONK: Close to 15. 4.7 times 3.

6

THE COMMISSIONER: I know, but I
want you to do it, to make it easier for me, I am
a metrical boy. Four times would make it 40
and five times would make it 80, wouldn't it?

9

MS. CRONK: No, excuse me,
Mr. Commissioner, I am sorry to interrupt but I do
think perhaps we have gone astray here and Dr. Ellis
can confirm it for me.

13

THE COMMISSIONER: All right.

14

MS. CRONK: Q. As I understand it
the first maximum measurement, Dr. Ellis, that one
might achieve if no fixed level was obtained would
be greater than 4.7.

17

THE COMMISSIONER: That is after
January the 10th or something. Just go back to
January the 9th, I just want to demonstrate a point.

20

MS. CRONK: I'm sorry.

21

THE COMMISSIONER: The first one is 5.

22

MS. CRONK: All right.

23

THE COMMISSIONER: The second one is
10, the third one is 20, the fourth one is 40, isn't

24

25



1

2

it, the fifth one is 80.

3

MS. CRONK: No.

4

THE COMMISSIONER: The sixth one is

5

160. Am I not right?

6

MS. CRONK: I really do think, sir,

7

that that is a little off. May I suggest this to
you?

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THE COMMISSIONER: All right.

9

MS. CRONK: And Dr. Ellis can confirm

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if I'm wrong.

11

Q. Dr. Ellis, leaving aside the

12

case of Janice Estrella for the moment, let's just

13

deal with pure numbers. If a level of greater than

14

4.7 is achieved the first time you do an assay?

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A. Yes.

16

Q. All right. If it is then

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diluted times 2 the results entered in your books

18

would be 2 times 4.7 equals 9.4. Am I right so far?

19

A. Yes.

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Q. All right. If the same

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sample was diluted again, this time diluted times 5

22

in five parts, would the result then not be 4.7 times

5 for an approximate result of 20 and change, 25.

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THE COMMISSIONER: Is that right?

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THE WITNESS: Yes.

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MS. CRONK: Q. Right. Similarly,
if one were to dilute the same sample times 10, in
10 parts, a volume of 10 parts, and the original level
was greater than 4.7, the end result would be 4.7
times 10 for 47?

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A. Yes, that would be the notation
that we would use, yes.

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Q. All right. And similarly then
if it was diluted times 20 it would be 20 times 4.7?

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A. Yes.

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Q. All right. Does that clarify
it, sir?

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THE COMMISSIONER: Well, it clarifies
it but I'm not sure if it is right though. How do
you go about diluting, just briefly, I don't want
to go into competition with you, I just want to
know roughly how you do it? What do you do? First
of all, you take this blood and you test it.

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THE WITNESS: Yes.

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THE COMMISSIONER: And you come out
and the best you can do is 4.7 - I would prefer 5
but if you want to use 4.7 that's fine.

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THE WITNESS: Whichever you choose.

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THE COMMISSIONER: All right. And
then the next time what do you do?



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THE WITNESS: You take, let us say
for the sake of simplicity 10cc of the serum or ml.

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THE COMMISSIONER: Yes.

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THE WITNESS: One volume.

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THE COMMISSIONER: Yes.

7

THE WITNESS: And we add one volume.

8

THE COMMISSIONER: The same amount
of water?

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THE WITNESS: The same amount of -
actually, I say buffer, which is equivalent to water.

11

THE COMMISSIONER: Yes, all right,
and then what do you do?

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THE WITNESS: So, that would then
be times 2.

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THE COMMISSIONER: Yes, all right,
and then when you don't get it again you just add
another one?

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THE WITNESS: We would then start
over.

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THE COMMISSIONER: Yes.

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THE WITNESS: Not with the dilution,
we would start over with the serum.

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THE COMMISSIONER: Oh, I see.

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THE WITNESS: We would then take the
1 ml of serum and add, say, 4 mls of buffer. So, it

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is 1.4.

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THE COMMISSIONER: Well, all right,

that's fine, I'm sure you know what you are doing

but if you can run a test on the blood plus the

equivalent of water, why can't you run a test on

that amount doubled, that is, that plus 3 equivalents

of water?

THE WITNESS: Yes.

THE COMMISSIONER: You could do that?

THE WITNESS: Yes. That's what we
were doing essentially, yes.

THE COMMISSIONER: Well then, I
don't think you got the right result. I may be
wrong but I don't think you have.

THE WITNESS: I am sorry, I think
the distinction that you are making is that you
first of all dilute.

THE COMMISSIONER: Yes.

THE WITNESS: And then you take the
dilution and you dilute that dilution again. This
isn't actually what we were doing.

THE COMMISSIONER: No, all right.
Well, I will accept your word for it and there is
going to be a lot of cross-examiners afterwards but
I don't know why you say times 5.



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THE WITNESS: Times 5 means that the result, when we obtain it, will have to be multiplied by 5 to obtain the correct result.

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THE COMMISSIONER: Okay, I give up, all right. I guess you know what you're doing and I certainly don't but I am surprised.

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THE WITNESS: Well, I'm sorry.

9

THE COMMISSIONER: No, no.

10

THE WITNESS: If the real result is 10.

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THE COMMISSIONER: Well, you can't get to, if you make the result 5, you can't get to the reading of 72 except by dilution of, whatever, 5, it would be 14 or 15. You have to do it 15 times, is that correct?

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MS. CRONK: 20. Depends on what the original reading was.

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THE COMMISSIONER: Well, no, no, but the original number was 5, if it was 4.7 or something but you would have to dilute that many times in order to get to that reading of 72.

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THE WITNESS: That's correct.

22

23

THE COMMISSIONER: You have something like 14, 15 or 16 or something like that.

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THE WITNESS: So, if we were to take



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one volume and add 14 volumes of buffer to that
amount and use that material in the same assay and
multiply the answer by 15.

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THE COMMISSIONER: You actually do
it this way. Assuming that you can read up to 5 the
first time, you take the same amount of this water-like
sustance, add to it, and then you take that same
amount again, again, and again and again and do it
through 14 or 15 assays, do you?

THE WITNESS: No, we would take a
volume of the original serum and add 14 times that
volume of diluted material.

THE COMMISSIONER: You do that in
one operation?

THE WITNESS: Or 20 times.

THE COMMISSIONER: You do it in one
operation?

THE WITNESS: Yes.

THE COMMISSIONER: You take the
serum and add 20 of this water substance?

THE WITNESS: Correct.

THE COMMISSIONER: And do one assay
then.

THE WITNESS: But you would actully
add 19. So that the total volume, the total amount



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would be 20.

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THE COMMISSIONER: All right.

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THE WITNESS: And this is why on

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the 16th of January, if I may move to page 2, the

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ultimate result that we start to produce, it says

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on the left hand side 3.7 times 20.

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THE COMMISSIONER: I only got one.

Have you got another page?

MS. CRONK: We will come to
January 16th in a moment, sir.

Q. Right now I would like to
be very clear, Dr. Ellis, as to what happened on
January 13th with this sample.

The page from the digoxin book
suggests possibly one of two things: first of all
that the sample was diluted. It is clear it was
diluted times 2 with the result that a level couldn't
be achieved and that the assay had to be repeated.

A. Yes.

Q. Are we clear on that?

A. Yes.

Q. Then we come to the next
entry for January 13th, and in light of what you
said a few moments ago I take it there are two
possible interpretations for that information. The
first is that the sample was diluted times 5 and
reassayed on that basis --

A. Correct.

Q. -- without a result being
achieved, thus requiring it to be repeated.

A. That would be my assump-
tion.

Q. All right.



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A. Because you have mentioned there were two dilutions, but I only have got the one "I". Okay? I have got H, I, J. If in fact there were two dilutions, in other words, four tubes, we should have gone I, J, K.

Q. I take it, then, doctor, in your view there was a second dilution times 5 but not a third dilution times 10?

A. Times 10.

Q. Right.

A. Unless what you say is correct and there was one tube times 5 and one times 10, but I don't think there were more than two tubes being assayed, and my assumption from this notation is it was done times 5 on that particular day, and that a note was left for the person in this notation "repeat times 10". In other words, try it again tomorrow times 10.

Q. All right, doctor.

Then when we come to January 14th we see that it was in fact repeated; this time at a dilution of times 10, and once again a result could not be achieved.

A. Yes.

Q. It had to be repeated.

Is that correct?

A. Yes.



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Q. Then we come to January
16th where you were a moment ago and we find those
entries --

THE COMMISSIONER: That is Tab 45?

MS. CRONK: Sorry, you are right,
sir. We come then to January 15th but it is at Tab
45, page 2.

Q. Do you have that, doctor?

A. Yes.

Q. On January 15th it appears
the same sample was again diluted, again by 10.

A. On January?

Q. On January 15th, diluted
again times 10.

A. Yes.

Q. Reassayed?

A. Yes.

Q. That result again is a
repeat result, meaning you couldn't get a result; you
had to do it again?

A. Right.

Q. So at this stage it had
been diluted times 10 on January 14th and it had been
diluted again on January 15th times 10, and both
results were off the maximum requiring repetition of
the assay?

A. Yes.



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Q. All right.

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Then we come to January 16th and the entry immediately below, doctor, and we see that the same sample was again diluted, this time times 20 --

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THE COMMISSIONER: What is the figure before that? 3.7, is it?

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MS. CRONK: It appears to be 3.7 times 20.

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Q. Am I reading that correctly, doctor?

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A. That is my --

THE COMMISSIONER: What does 3.7 mean?

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THE WITNESS: That would be the result obtained on the calibration curve that would only go up to 4.7, so the actual result they would obtain on that occasion was 3.7 with this very, very diluted material.

23

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MS. CRONK: Q. And then when diluted times 20 there is an indication, not looking at the results category, doctor, but just looking at the entries that appear beside Janice Estrella's name, it appears that the first time it is diluted times 20 the result is in fact 74 nanograms.

Do you see that?

A. In other words, 3.7 times 20.



BB5

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Oh, yes.

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Q. I am looking at the actual
number 74.

4

A. Oh, yes.

5

Q. Which is encircled beside
her name.

6

7

A. Yes.

8

Q. That appears to have been
the result.

9

10

A. Yes.

11

Q. And then if you will

bear with me, Mr. Commissioner --

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THE COMMISSIONER: Yes.

13

MS. CRONK: Q. If we look

14

further down the page we see the same sample number
which has again been diluted times 20, and this
time looking at the numbers encircled it appears
that the result was 70 nanograms. Is that correct?

15

16

17

A. Yes.

18

19

Q. So that the mean of those
two results was taken to report a level of 72 nano-
grams for this sample; is that correct, doctor?

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A. Yes.

22

Q. Am I reading that

23

correctly?

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A. Yes.

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Q. So that in that case we



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have a dilution twice times 20 of what you have described as very diluted material, and the first time a result of 74 is achieved, the second time a result of 70, and when the technologist or technician was entering that final level in the book the level was chosen to be 72, the mean between the 70 and the 74 reading.

A. Yes.

Q. Do I have that correctly?

A. Yes.

Q. All right.

Now, doctor, with respect to that level of 72 nanograms can you tell me once the assays have been completed on January 16th, was that result - by that I mean the 72 or indeed was the result of 74 or the result of 70 brought to your attention?

A. Yes, it was.

Q. All right. Had you ever before in your experience, doctor, encountered a digoxin level in the range of 70, 72, 74?

A. Not to my recollection, no.

Q. Were you surprised in this case when a level that high was reported back to you?

A. Surprised?



BB7

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Q. Did that level startle you?

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A. It appeared to be high, yes.

4

Q. Well, in your prior

5

experience, doctor, you have told us that your

6

understanding was as to a therapeutic level for

7

digoxin and a toxic level, this level, the second

8

post mortem sample ever assayed for digoxin in your

lab was many, many times that range.

9

A. Yes.

10

Q. Was it not?

11

A. Yes.

12

Q. The level was very high

indeed?

13

A. Yes.

14

Q. When you learned of that

15

level, doctor, what did you then do?

16

A. I instructed my techno-

17

logist to report the level of 72.

18

Q. All right. To whom?

19

A. In the usual way.

20

Q. All right. In this

case that would be to whom?

21

A. The usual way -- I believe

22

that we produced -- I have no recollection of a

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direct telephone call from my technologist to

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Pathology in relation to this sample, and I certainly didn't telephone Pathology at this particular time.

The background is that -- the reason why you telephone results is so the patient does not receive the next dose of digoxin if the digoxin level is high.

This is the second or the first one that was of note autopsy sample; obviously we couldn't help that particular patient and so the urgency with which that result was reported was less than the usual telephone urgency.

Q. Yes.

A. And basically my own view of this individual result was that this was analytically satisfactory from an analytical point of view.

I personally did not know why the doctors had ordered it. My interpretation of this result to my staff and in discussions after that were related to very high levels seen in blood - and this is living patients usually -- well, this is living patients. The very high levels that are seen immediately after a dose of digoxin is given, I think we have indicated before that unless you



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know exactly when that digoxin dose has been given
you cannot interpret a result.

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So having seen this incredibly
high result I presumed or I assumed that the
digoxin dose had been given shortly before death,
and nothing more from that.

7

8

Q. Doctor, may I just stop
you there.

9

10

11

A. Yes.
Q. You are explaining -- you
told us what your reaction was.

12

13

A. That was my conjecture.

14

Q. What your concerns were.
You told me first in that regard that you thought
the level of the test was analytically satisfactory.

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A. Yes.
Q. Do I have that correctly?
A. Yes.
Q. And by that do I correctly
take you to mean that you had no concerns about the
performance of the assay itself?

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A. That is correct in that
whereas most samples in the laboratory are analyzed,
two tubes on one occasion, this result that had been
obtained had been analyzed on multiple occasions.



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BB10 2 So from an analytical point of view I was satisfied
3 with that result.

4 Q. You were then satisfied
5 that nothing had technically gone wrong with the
6 assay itself?

7 A. That was my overriding
8 concern about this particular number of 72.

9 Q. Did you satisfy yourself
10 that had not happened; that in fact nothing had
11 gone wrong with the assay by virtue of the fact that
12 it had been diluted several times?

13 A. So many times, yes. Yes.

14 THE COMMISSIONER: Can I just ask
15 one question about this dilution.

16 Do I understand that every time
17 you use a dilution you use up some of the blood?

18 THE WITNESS: Yes.

19 THE COMMISSIONER: It can never
20 be used again?

21 THE WITNESS: That is correct, yes.

22 THE COMMISSIONER: So you run a
23 risk in just going up by 2s. You would want to
24 eventually -- you could very easily run out of blood
25 available for this.

THE WITNESS: Very much so.



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THE COMMISSIONER: So it is probably sensible to bracket it; if you are suspicious of a very large reading it is probably wise to start with 10 or 20. But you weren't suspicious?

THE WITNESS: No.

THE COMMISSIONER: But you could have easily run out of blood in this instance except I suppose you had such a huge quantity from the pelvic cavity you would never run out?

THE WITNESS: I think the sample requisition stated that there were two samples.

THE COMMISSIONER: Yes.

THE WITNESS: Samples A and B.

THE COMMISSIONER: Yes.

THE WITNESS: That came in with the same number, one of which seemed to have this association with a possible diluted specimen.

THE COMMISSIONER: Yes.

THE WITNESS: It was only that particular one, if my recollection is correct, only that particular one that had sufficient sample to keep diluting and diluting and diluting.

If you remember on the first occasion when the A and B were analyzed I think we had obtained a result of greater than 4.7.



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THE COMMISSIONER: 4.7, you

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didn't have enough blood to go on from there?

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THE WITNESS: That is right.

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MS. CRONK: Q. Then, doctor --

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sorry.

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THE COMMISSIONER: I am thinking

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and that is always a dramatic event in my life. It

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is the system because clearly it would be better

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if you are going to be dealing in figures like this

and you have only a limited amount --

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THE WITNESS: Yes. You start

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with a very, very tiny amount.

13

THE COMMISSIONER: No, but if

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you can dilute -- I don't quite know why -- if you

15

just need that amount of blood, to dilute as many

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times as you like, but you only do it once. If you

17

were to dilute it 10 or 20 times would you not still

18

get an accurate reading instead of diluting it twice?

19

I just don't understand why the twice.

20

THE WITNESS: I appreciate the

point you are trying to make.

21

You are saying that a certain

amount of blood arrives in the laboratory.

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THE COMMISSIONER: Yes.

23

THE WITNESS: And we will analyze

24

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BB13

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a part of it neat.

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THE COMMISSIONER: Yes.

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THE WITNESS: A part of it as

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it stands and throw it away. Okay. Because --

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THE COMMISSIONER: You never use

7

it again.

8

THE WITNESS: We can never use

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it again and in fact as part of the assay it gets
consumed.

10

THE COMMISSIONER: Yes.

11

THE WITNESS: It gets thrown away.

12

THE COMMISSIONER: Yes. You only
have got an opportunity for one more assay.

13

THE WITNESS: This would depend

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on the amount received.

15

THE COMMISSIONER: All right.

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Let's say you get enough for two;

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you get enough for two, and I have seen this happen.

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In many cases you have said greater than 10 and we
can't go any farther.

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THE WITNESS: Yes.

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THE COMMISSIONER: I just ask

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why under those circumstances you don't dilute 20,

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30, 40 times to make sure you get one more reading

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that will tell you what the answer is.

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THE WITNESS: Yes. Basically because our experience is that in 98% of the cases simply by doing a single-shot dilution of 50 micro-litres into two tubes we get the answer.

THE COMMISSIONER: You do it once and you don't get the answer --

THE WITNESS: Right.

THE COMMISSIONER: -- that might make you suspicious?

THE WITNESS: Yes.

THE COMMISSIONER: And you say there is something wrong with this blood; there is too much digoxin in it. And then what do you do? You decide you will do it once more. But really what I am getting at does it make any difference as far as the accuracy is concerned whether you dilute it twice, four times or 20 times?

THE WITNESS: Yes, in a sense it does because if you dilute it 20 times the level is only just greater than 5, but then whatever inaccuracy there is in that result that is obtained you will multiply that inaccuracy by 20.

If you dilute it on the other hand times 2 whatever inaccuracy there is associated with that result will be increased times 2 by the dilution



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BB15 2 factor, so the best result we can get is a straight
3 assay.

4 MS. CRONK: Q. And by straight
5 assay, doctor, you mean neat?

6 A. Neat, yes.

7 Q. Without any dilution at
8 all?

9 A. Yes. And in relation to
10 my 98% of cases that we can do straight I would say
11 that, guessing in terms of numbers, that we then go
12 to 99.5% on the ones that we can get 1 in 2.
13 Okay. And the numbers that we have to dilute 1 in 20
14 or --

15 Q. Are very rare indeed?

16 A. Very rare indeed.

17 Q. And in this case, doctor,
18 we know that that happened and you have told us that
19 once the result, the level, was made known to you
20 you first satisfied yourself that analytically
21 the assay had been performed correctly?

22 A. Yes.

23 Q. You didn't have any
24 concerns on that level?

25 A. Yes.

THE COMMISSIONER: If I could just



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ask one more question while we are on this subject
and then I will keep quiet.

If you look at Exhibit 45 from
the preliminary inquiry, you look at Item C, Item G,
I take it those were two separate assays requiring
two separate vials or whatever they are of blood.
Is that right? Page 2.

THE WITNESS: Page 2, yes.

THE COMMISSIONER: You see C,
in the bottom part of it, C and G were assays of the
same sample but they were separate -- not samples --

MS. CRONK: Assays.

THE COMMISSIONER: -- separate
assays but they used separate blood? Is that
correct? You couldn't use the same blood?

THE WITNESS: In making a 1 in
20 dilution we may have ended up with quite a large
volume that could have been used for both those --
both those independent assays from then on.

MS. CRONK: Q. May we be clear
about this, Dr. Ellis, and the Commissioner's
question, as I understood it all of those assays
that were done on the 15th and on the 16th of
January were on the same sample of blood, it was
the same blood; it was just a different part of the



BB17

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sample?

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THE COMMISSIONER: Yes.

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A. Yes.

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MS. CRONK: Q. Is that correct?

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A. That is correct.

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Q. You are not talking about different blood. It was the same sample, same blood specimen, and it is just that in each case you were using another part of it. You weren't using the same part.

11

A. Yes. On sequential days we would use a separate part of that blood.

12

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Q. That is right.

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A. On the 16th of January my technologist would have two options: to make a dilution 1 in 20 and analyze it effectively four times to give him C and G, or to take one part of the blood and dilute it times 20 and assay it and take another part of the blood sample, dilute it times 20 and assay it.

20

Q. That is what he chose to do?

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A. I don't know which he chose to do.

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Q. All right. It appears,



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doctor, from the entries on January 16th, however,
that there were two assays at 20 times dilution
run, does it not?

A. Yes.

Q. Does that not suggest that
one part of the sample was diluted times 20, was
assayed, resulted in a level of 74, and then another
part of the specimen was again diluted times 20,
again assayed quite separately from the other one,
and this time resulted in a level of 70?

A. Yes. The subsequent
assay was quite independent of the other one. The
G assay was quite independent to the C assay.

Q. I'm talking only about G.
Oh, I am sorry, C and G, yes.

A. Okay. What I can say is
that those are independent assays, almost like a
different patient.

THE COMMISSIONER: Different
blood, too, because particularly if it is contaminated
would they not be different blood?

THE WITNESS: No, I don't think so.

THE COMMISSIONER: I don't know,
but if it was contaminated wouldn't it be contaminated
in one part of the sample more than another or would



BB19

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it all be mixed up?

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THE WITNESS: It would have been
mixed up, yes.

5

6

THE COMMISSIONER: Any contamination
of any part of it would be the same?

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THE WITNESS: It should have been
dispersed, yes. But I cannot tell whether separate
portions of the same blood sample were taken for
Analyses C and G, but I believe from the analysis
point onward, from the two tubes onward right through
the immunoassay procedure effectively four tubes
were being handled in relation to that sample.

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MS. CRONK: Q. Yes. And just to
be very clear again, you were satisfied that in
consideration of the results the assay as it had
been performed was performed correctly?

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A. Yes.

Q. All right. And you have
told us as well, doctor, that you had a concern with
respect to this level once you were made aware of it,
that there might have been a problem in terms of the
time --

A. Well --

Q. Just if you could wait
for the question, Dr. Ellis.



Ellis
dr.ex. (Cronk)

BB20 2

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A. But you said I expressed concern, did you say?

Q. I am sorry. You were explaining earlier your reaction to this level and you told me two things: first that you thought it was analytically satisfactory.

A. That is correct.

Q. All right. Secondly I understood you to say that you thought it was high and you discussed with your technologist at the time the possibility that the sample which had been assayed had been taken in too close proximity to the time at which the last dose of digoxin had been administered?

A. Correct.

Q. Do I understand that?

A. Yes.

Q. Was that not a concern in your mind in terms of trying to arrive at an explanation for this level? I put it no higher than that. That was one of the things that you thought might explain this level?

A. That was one of the things that I felt might explain this level.

Q. All right.



BB21 2

1
A. I regarded that as the
most likely explanation.

4 Q. All right.

5 A. To the point of dismissing
6 other possible reasons why that might have occurred.

7 Q. All right.

8 Then let's examine what you
9 thought was the most likely explanation and that is
10 the time interval between when the last dose is
given and the time when the sample itself was taken.

11 From your earlier evidence, doctor,
12 we have looked at the assays that were conducted
13 on January 8th on this child, the assays that were
14 conducted on January 9th and the assays on January
15 7th, and you told me that on January 7th on a
16 different sample, also a blood sample from an
17 artery, the level was greater than 5 but it was
18 reassayed the following day and a result of greater
19 than 9.4 or greater than 10 was achieved, but that
20 that greater than 9.4 or greater than 10 result was
21 not reported because the reporting of the greater than
22 5 level would have been sufficient to put, I took it,
23 the clinicians on notice that digoxin should be held.

24 A. Yes.
25



DM.jc
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Q. Do I have that correctly?

A. Yes, that is correct.

Q. All right.

A. The child was showing some evidence of - I am sorry, the child was - appeared on the basis solely of the results to be going through an episode of digoxin toxicity insofar as you can define that from the results only.

Q. The level of greater than 5 that was in fact reported was well above what you understood to be the threshold of the toxic range?

A. That is correct.

Q. That is on January the 8th and January the 9th?

A. Yes.

Q. And you have also told me that on January the 9th, I am sorry, January the 8th, another sample was assayed and this one had a result of greater than 4.7. It is well assayed the next day on January the 9th, and this time a level of 7.8 was achieved, but you told me that 7.8 level was not reported to the ward, again for the same reason that because the day previously a greater than 4.7 level had been reported, that level, the 4.7 would be sufficiently high to alert the clinicians that digoxin



CC.2

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should be held; do I have that correctly?

3

A. Yes, and because a subsequent sample I think was being analyzed, a fresh sample as opposed to yesterday's.

4

5

6

Q. That is the one I am talking about, the one that resulted in a level of greater than 4.7 was assayed on January the 8th, was reported by telephone on that day, you have told us. As I understood your evidence that would have been sufficient to put the clinicians on notice that digoxin should be held; do I have that correctly?

7

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A. If your recollection of these events is correct, yes.

13

14

Q. No, I am talking about your evidence this morning, Doctor?

15

16

A. Well, if that is what I said this morning with the books in front of me then that is okay.

17

18

Q. My question to you at this point, Doctor, is with that in mind --

19

20

A. Yes.

21

Q. -- by January the 9th there has been two levels reported to the ward, one of greater than 5, correct?

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23

A. Yes.

24

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CC.3

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Q. And one of greater than 4.7,

3

correct?

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A. Yes.

5

Q. I am sorry, was that yes?

6

A. Yes.

7

Q. Both of those levels, Doctor,

8

were outside, beyond the threshold of the toxic range
as you understood it?

9

A. Yes.

10

Q. In those circumstances did you

11

assume, Doctor, that digoxin would have been held on
this child?

12

A. Yes.

13

Q. If that be the case, Doctor, and

14

you then received another sample on January the 11th,
which was then assayed a number of times and resulted

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in a level that we have seen of the mean result of

17

72 nanograms, how could you then assume that if the

18

sample had been taken too close in time to the time at

19

which the dose had been administered if you had been

20

presuming that digoxin had been held?

21

A. Isn't there one element in this

22

that you are forgetting, and that element is that the

23

last result was not greater than 4.7 but was reported

24

as 4.7. In other words, we saw a peak and we saw it

25



CC.4

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coming down, isn't this the situation?

3

Q. Yes, that is correct, Doctor.

4

A. The last result you have just mentioned was greater than 4.7?

5

6

Q. Yes, and then on the 9th one of 4.7 is reported.

7

8

A. 4.7 ---

9

THE COMMISSIONER: Miss Cronk, where is that, I am getting mixed up with this Exhibit 45 and Exhibit 46.

10

11

MS. CRONK: I am sorry, sir.

12

THE COMMISSIONER: Could you tell me - I take it ---

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MS. CRONK: This is under Tab 46, sir.

15

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THE COMMISSIONER: Yes, I know. It starts on the 15th of January, this is Exhibit 45 and it seems to go on to the 24th of March, which is of course a very important day. The other one starts at the 17th of October and seems to go on ---

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MS. CRONK: The 17th of October, 1979, and goes on to January the 12th, 1981.

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THE COMMISSIONER: Yes, that is right, I am sorry.

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MS. CRONK: Q. Doctor, if I can refer you to page 169 at Tab 46.

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A. Yes.

Q. And may we examine again the events before the postmortem sample, right.

A. Yes.

Q. You have three levels reported to the ward; the first is a level of greater than 5, that is an assay result achieved on January the 7th.

A. Okay.

Q. That is on page 167, Doctor.

A. Oh, okay, yes.

Q. Is that correct?

A. I wasn't taking exception to those points, right. I was just taking exception to the fact that this had been a very high result of greater than 10 at one stage, it had slowly come down to 7-point-something and by the Friday the 9th of January, on the second page, 169, the result that we were actually reporting then is 4.7.

Q. That level, Doctor --

A. No greater than 4.7.

Q. I accept that, Doctor. I just wish to be clear about what your concerns were?

A. Well, my concerns are that we have seen an episode of elevated digoxin level that appears to be coming down, okay.



CC.6

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Q. Yes, Doctor.

3

A. And eventually that particular

4

digoxin level if the child's metabolism is okay, will
come back into the normal range at some point.

5

6

Q. Doctor, is the level on January
the 9th the last antemortem level reported as 4.7?

7

A. Yes.

8

9

Q. That level I take it we can
agree is beyond the threshold of the toxic range as you
understood it?

10

11

A. It is, yes.

12

Q. It is well beyond the 3.5?

13

A. That is correct.

14

Q. In those circumstances, would
you assume at that point that digoxin would continue
to be held with respect to that child?

15

16

A. On that day, yes, unless there
were overriding clinical indications of starting it up
again.

18

19

Q. If I understand your evidence
correctly, Doctor, given that you were concerned when
you learned of the level of 72 nanograms that the
sample may have been taken in too close a point of
time to the time of the last administration of digoxin?

20

21

22

23

A. No, again you said I was

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CC.7

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concerned but, I wasn't "concerned but", I rationalized it on the basis that this had probably happened. I wasn't concerned at this particular stage with this result, it wasn't my concern.

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Q. All right, Doctor, I am sorry.

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A. It was a sample supplied to the laboratory by a pathologist who has the responsibility of determining the cause of death, and who happened to in the course of his investigation to send an additional sample to us. Our responsibility then, as I saw it at that particular time, our responsibility is to produce a result on the basis of the sample that he sends us and to send it back to him. Our responsibility is not to be concerned with anything, you know.

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Q. I didn't intend to suggest that there was concern about anything sinister, Doctor.

20

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A. No.

22

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Q. I am concerned only to explain how that level could have resulted. As I understood your evidence you thought that one possibility, and



CC.8

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you have said the most likely explanation you thought,
was that that level of 72 could have resulted because
the sample was taken too soon after the last dose
had been given, do I have that correctly?

5

A. Yes, you have that correct.

6

7

Q. Now with that in mind, were you
then assuming, on January the 16th when that level
became known to you, that the child had again received
digoxin during life, prior to death, notwithstanding
that the three antemortem levels of which you were
aware were above the threshold amount of the toxic
range?

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A. Okay. How do you put together
every single detail of the previous week in the way
that we are putting it together now?

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Q. All right, Doctor. Did you,
Doctor, when you were examining possible explanations
for this level, contact Dr. Taylor or anyone else in
the Pathology Department, to determine if in fact the
sample had been taken too close in time to the date
of the last dose?

21

A. No, I didn't.

22

23

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Q. And I take it then, Doctor,
that on January the 16th when these possible
explanations were going through your mind, you were



CC.9

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not aware of the fact that Janice Estrella did not
receive digoxin for four days prior to her death?

3

4

A. I am sorry?

5

6

Q. I take it on January the 16th
you were not aware of the fact that Janice Estrella
had not, as it happens, received digoxin for four days
prior to her death, you were not aware of that?

7

8

A. I wasn't, no.

9

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Q. Doctor, you indicated as well
that a second assay was being conducted on a different,
a separate sample at the same time that this sample
originally was assayed. I would ask you again to look
at page 169, and that is Tab 46, Doctor.

14

A. Yes, thank you.

15

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Q. Doctor, we see on January the
12th that the second sample, Sample No. GA9246 was
as well received from Pathology and it appears to be
a sample taken on January the 11th and the assay
result was greater than 4.7, right, that is the one to
which you drew our attention previously?

20

A. Yes.

21

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Q. And there is as well, Doctor,
a handwritten notation, again beside the name Janice
Estrella, indicating that that sample was post mortem
(from vein), do you see that, Doctor?



CC.10

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A. Yes.

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Q. Doctor, was it your understanding

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on January the 12th when this assay was done that this

5

was a sample of postmortem blood obtained from the

6

vein, did you know that then when it was being assayed?

7

A. Well, it also says postmortem

8

blood, doesn't it?

9

Q. Yes.

10

A. So then or around that time.

11

Q. That was drawn to your attention?

12

Q. There is no indication with

13

respect to that specimen, Doctor, in your digoxin books

14

that the specimen was possibly diluted, is there?

15

A. No, this in contrast to the
possibly diluted, a notation "from vein" was given.

16

Q. All right. Was there any issue

17

or question of which you were aware at the time that

18

that second sample, the one from the vein might be

19

possibly diluted?

20

A. No.

21

Q. And Doctor, with respect to

22

those two levels, dealing with the events of January

23

the 12th, you then have one sample which has resulted

24

in a level of greater than 4.7; was the quantity of

25



CC.11

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the sample sufficient to permit further dilution on
that sample? To help you it is my understanding it
was not?

4

5

A. GA9246?

6

Q. That's right.

7

A. I don't think there was
sufficient otherwise we would have attempted to do it.

8

9

Q. So on that day you have one
fixed level of greater than 4.7, that is off your
maximum, and you have another but you don't know what
the amount is, the fixed level, you don't discover
the actual fixed level of that second sample until
some four days later on January the 16th when it is
clear as a result of the assay, that the level was
in fact 72 nanograms; do I have that correctly, Doctor?

10

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A. Yes, that our result was 72.

:53 (2)

16

17

Q. On January the 12th when the
first fixed level was available for reporting, the
greater than 4.7, was that orally reported to the
Pathology Department?

18

19

20

A. I don't think - it wasn't by me
to my recollection. There was the outstanding order,
if you like, that the results first of all would be
telephoned. Because of the kind of unusual nature of
this particular sample, I don't know for sure that
that occurred.

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CC.12

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Q. What was the unusual nature of
this sample, Doctor?

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A. Well, because it was from
Pathology and so we could no longer stop the next
digoxin dose, which was the major overriding reason
for telephoning the result.

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Q. I see, so I take it you don't
know whether this one that was greater than 4.7 was in
fact telephoned to Pathology?

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Q. I take it you don't recall
instructing them to do so?

A. No.

Q. And you yourself did not do so?

A. No.

Q. Then we come to January the 16th,
Doctor, and the results of both of those series of
assays, if I can describe it that way, were available
to you and you know you have one level on one sample
of greater than 4.7 and a level of 72 on another
discrete, separate specimen?

A. Yes.

Q. At that stage ---



CC.13

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A. Yes, of unknown quality.

3

Q. Because of the possible dilution

4

issue?

5

A. Yes.

6

Q. Did you at that stage, Doctor,

7

consider it appropriate to contact the involved

8

pathologist to determine whether or not the sample

9

that resulted in the 72-nanogram level had been

10

A. Had been diluted?

11

Q. By a contaminant? Was it at

12

that stage considered by you appropriate to do that,

13

to contact the pathologist?

14

A. I didn't do that.

15

Q. Did you at that stage have any

16

discussion with any of the clinicians who had been

17

involved in the care of the child during her life to

18

determine in fact what the history of the administration

19

of digoxin had been, and what the doses were that had

20

been administered to her?

21

A. I don't believe I did, no. Can

22

I say that in Biochemistry we receive a large number

23

of samples during the day. If there is anything we

24

can do to help the child when the result becomes

25

available by making telephone calls, then we would



CC.14

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attempt to do so, but in this particular case ---

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Q There wasn't.

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A. There wasn't as far as I was concerned. We can't telephone every single result, even if it is unusual but - I am sorry, except in relation to digoxin. We have to make some assumptions in the overall operation of the Department. One assumption is that if somebody sends you a specimen they have some reason for sending you that specimen. That is one assumption we make.

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The second assumption that we make is that when you produce a result for them they are going to have the knowledge, or some way of knowing what that result means in the particular context in which they requested that sample.

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The third assumption we make is if they don't know that, if they want help, then they phone you and they say, hey, we don't believe this result; or they phone you and say, what do you think about this, have you seen one like this before? So, my main concern was as accurate as it is send it out then, let them figure out what it means, I can't tell them what it means.

23

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Q Doctor, in this case, given that those were the assumptions at the time that were



CC.15

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necessary in your view to run the department, in this case after those two levels were available, that is by January the 16th those were available, I take it that in due course a Biochemistry clinical printout was made available and forwarded to Pathology reporting those results?

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A. I assume that that happened, that was the procedure.

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Q. Were you then contacted at any time during the month of January, up to the end of January, by anyone from the Pathology Department to discuss either or both of those levels?

13

14

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A. Not to my recollection.

17

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Q. During the month of February were you contacted by anyone from the Pathology Department to discuss either or both of those levels?

A. I believe the only contact that we had followed the death of Pacsai.

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Q. And that would be after March the 12th then, 1981, that is the date that Kevin Pacsai died, right?

A. Yes.

Q. Doctor, up until that time from January the 16th through until March 12th, 1981, do you recall being contacted by any clinician, any



CC.16

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cardiologist in the Hospital, to discuss either or
both of those two levels on Janice Estrella?

3

4

A. I don't recollect any conver-
sations in relation to that.

5

6

Q. I am sorry?

7

8

A. In relation to the autopsy
samples you mean?

9

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Q. I am talking about the two
autopsy samples, the level of 72 and the level of
greater than 4.7?

11

12

A. Yes. You see, those results
originated from the Pathology Department so they would
be sent back to the Pathology Department.

13

14

Q. I understand that, Doctor. My
question was merely whether or not you, or to your
knowledge, any of the technologists in your department
were contacted by any of the cardiologists involved
in the care of the child during life to discuss those
levels at some point subsequent to the reporting of
those levels to Pathology? I take it your answer is no?

15

16

A. Not to my knowledge.

17

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Q. And more specifically, Doctor,
were you contacted at any time up to March 12, 1981,
by Dr. Robert Freedom of the Cardiology Division to
discuss either or both of those levels?

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CC.17

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A. Was that prior to the death of
Pacsai?

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Q. Yes, March 12 is the day that
Kevin Pacsai died?

5

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A. I don't recall any conversation
that we might have had.

7

8

Q. And Doctor, with respect to the
vein sample which resulted in a level of greater than
4.7 --

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A. Yes.

11

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Q. -- with respect to that sample,
I take it that we can agree that because the only
result that was available on the assay that was
conducted was the result of greater than 4.7, that we
cannot be certain what in fact that level was?

13

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A. No.

16

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Q. It was simply off the maximum
of the recording of the test?

18

A. That is correct.

19

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THE COMMISSIONER: Was there any
indications in the computer printout, or any place else
that you couldn't do another assay? I am looking at
page 158 which I guess of the ---

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22

MS. CRONK: Exhibit 91, sir.

23

THE COMMISSIONER: Exhibit 91. Was

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CC.18

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there any indication that you couldn't do any more
than that? I think it was Dr. Taylor who assumed
there would be another report on that.

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THE WITNESS: On the second blood
sample?

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THE COMMISSIONER: That is the vein
sample.

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THE WITNESS: The vein sample? Does
it say NSQ to repeat on the bottom of the report?

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MS. CRONK: No I believe it is the
Commissioner's point ---

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THE COMMISSIONER: No, it doesn't say
anything on the computer printout as to whether there
is going to be another one or not. Dr. Taylor said
that he - I am not too sure, I think he may have
decided it was just one sample that was given but he
expected that the 4. -- he didn't look, I can pretty
well understand, or take in the specimen number, but
he saw presumably shortly after the 13th of January,
shortly after - do you want to turn to page 158 of
Exhibit 91?

21

MS. CRONK: I am not sure the Doctor
has it, sir.

22

23

THE COMMISSIONER: I am sorry.

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MS. CRONK: Mr. Registrar, could you



CC.19

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give Dr. Ellis Exhibit 91, the medical record of
Janice Estrella.

3

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THE WITNESS: Looking at our digoxin
book if you say that the computer printout didn't have
that notation I can well understand why it didn't.

5

6

7

THE COMMISSIONER: What happens, you
see, is that it gets - on page 158 you will see the
greater than 4.7, and then go back to page 157, it
gets 72 some days later. Apparently page 156 there is
also a level of 72. I don't quite understand that,
both seem to have an asterisk, so they are both
reported for the first time.

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MS. CRONK: The two results, sir, on
this sample are the two reports that deal with the
greater than 4.7 and they are at page 159 and 158.

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THE COMMISSIONER: Yes. But neither
of those as I understand it indicate there is going to
be another ---

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Can you perhaps tell me. I assume that the asterisk being on page 158 that first report came with the computer printout dated the 13th of January, '81. Am I correct on that?

THE WITNESS: Yes.

THE COMMISSIONER: 4.7.

THE WITNESS: Yes.

THE COMMISSIONER: And the second one, or perhaps the second, third or fourth, I don't know, page 159, I don't see anywhere there an indication that there is not sufficient quantity to make another assay. If you look at page 156 and 157, they seem to be identical reports except different dates. Do you see the report of the 72 coming in presumably for the first time?

THE WITNESS: Yes.

THE COMMISSIONER: Dr. Taylor, as I understand it, really assumed that the 72 and the 4.7 were the same and he expected after the greater than 4.7 to have another and then of course when he got the 72 he decided that that was not a valid return. All I'm asking really, is it part of your computer printout to tell that you can't go any higher than the 4.7. I mean, does that happen. If it doesn't happen that's fine, it wouldn't happen



DD2

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here, but does it happen sometimes? You put not
sufficient quantity if you can't make any test.

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THE WITNESS: If you can't do any
test at all, right.

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THE COMMISSIONER: If you can't dilute
you don't put anything in.

7

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THE WITNESS: If we use all the
sample and obtain the result of greater than 4.7
and that's as far as we can go.

9

10

THE COMMISSIONER: Yes.

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THE WITNESS: That is the result
that we would put into the computer.

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THE COMMISSIONER: Yes. But you don't
tell them that there won't be another one.

15

THE WITNESS: That's correct.

16

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THE COMMISSIONER: You see if
somebody were waiting for the results of the 4.7
he might well assume that the 72 that came in a
few days later was the same, was the 4.7 diluted
several times.

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THE WITNESS: But isn't that a
different specimen?

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THE COMMISSIONER: But I don't
think he noticed that and I really don't think most
people would. I may be wrong. I don't think most



DD3

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people would check the number.

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THE WITNESS: Yes.

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THE COMMISSIONER: No question it is

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a different sample, 4.7 is from the vein and 72 is

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from the pelvic cavity.

7

THE WITNESS: The greater than 4.7

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is from the vein, yes, and the 72 is the questionable
one.

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THE COMMISSIONER: Well, I just

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mention it to you because if - you see, greater than

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4.7 can conceivably be 4.8.

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THE WITNESS: Yes.

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THE COMMISSIONER: Which is not that

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alarming.

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THE WITNESS: Sure.

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THE COMMISSIONER: But it can also

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be 72.

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THE WITNESS: Yes.

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THE COMMISSIONER: Which is very

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alarming. I just wondered if you knew at that time,

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as you would know with this one, the 4.7, that you

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can't go any farther, if your computer has any

symbol for that to tell anybody.

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THE WITNESS: We could have written

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any comment we liked in relation to that sample as

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a comment. In fact, that didn't occur on this particular occasion. I think in my preliminary hearing testimony I may have given this result as 4.7 with insufficient to repeat.

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THE COMMISSIONER: Yes.

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MS. CRONK: Q. Doctor, in addition to the possibility of making a notation on the biochemistry printout report, had the level of greater than 4.7 been reported by telephone on January 12th when that level was available? Is it not possible that during the course of that reporting discussion it could have been mentioned to pathology that no further sample was left to permit a further dilution. I take it that is a possibility.

16

A. It is a possibility, yes.

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Q. Doctor, with respect to that sample that lead to the greater than 4.7 result would I be correct in assuming that at the time it was assayed you did not know the site from which the sample was taken other than the fact that it was a vein. That was the only information available to you?

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A. You mean in respect of the sample from the vein or the possibly diluted sample?



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Q. The vein. The sample from
the vein.

A. Yes, that's all we knew.

Q. And did you know anything
about the circumstances under which that sample
had been taken, the one from the vein?

A. No.

Q. All right. And similarly
with respect to the sample that resulted in a level
of 72, did you know at that time the site from
which that sample had been taken? You will recall
that there is an O, another on the digoxin entries
in your digoxin books for that.

A. Yes.

Q. You had no information as
to the site from which this sample was obtained?

A. No. But I believe a sample
that looked like blood had been received, so, it
would be reasonable to assume that it was a blood
sample as opposed to another fluid.

Q. But I take it, Doctor, you
did not have any information through that period
from January 12th through to January 16th as to
the circumstances under which that sample had been
taken, the method used or the timing?



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A. The milking of the veins and all this kind of thing I learned about very much later.

Q. Well, I am talking about now the pelvic cavity sample as it happens.

A. Yes, sure.

Q. And I take it you did not then have any information or knowledge as at January 16th as to the circumstances under which that sample had been taken?

A. No, I didn't.

Q. All right. And Doctor, when you learned of those two levels, the greater than 4.7 level and the level of 72 nanograms you have told me that you did not at that stage know that Janice Estrella had not received digoxin for four days prior to her death?

A. No.

Q. All right. Had you known that, Doctor, had you known from whatever source of information that that was the case, would those two numbers at that stage have caused you sufficient concern to contact the Pathology Department at that stage and enquire further into the matter?

A. That's speculation.



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DD7

Q. All right. You don't know how you would have reacted?

A. I mean, I hope I would have done but...

Q. Well, that's fair, Doctor. Mr. Commissioner ---

A. Can I just mention one thing as well in relation to quality of samples in general in that I was here just for Dr. Cutz' last few words of his testimony and he was indicating, you were asking him about potassium results and he was saying you can't really rely on that result the sample is hemolyzed. Okay, if anybody tells us that the sample that they are giving us is anything - that the quality of the sample is possibly compromised, then any significance that we might attach to that sample is reduced. If they tell us it is hemolyzed, if they tell us it is full of lipids, if they tell us it is contaminated with something, we immediately detune if you like in terms of our sensitivity to the results that we finally obtain on that sample.

Q. I understand, Doctor. And in this case, although you don't know who provided that information, when or how, it is clear that the technologist who conducted these assays had been



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informed there was an issue about at least the
one sample, the pelvic cavity sample, correct?

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A. Yes.

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Q. All right. But there was
no such indication with respect to the leg vein
sample?

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A. That's correct.

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Q. All right.

Mr. Commissioner, may we take our
break now?

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THE COMMISSIONER: Yes, all right,
we will take 15 minutes.

13

---Short recess.

14

---Upon resuming.

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THE COMMISSIONER: Ms. Cronk, this
document that has January 13th and January 14th on
it, should it be added to one or the other of these
two?

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MS. CRONK: I neglected to ask you
to add it in. It should be properly attached to
Tab 45, Exhibit 32B. It is the first page of that
book.

22

THE COMMISSIONER: Yes, all right.

23

MS. CRONK: 45A, sir?

24

THE COMMISSIONER: Well, it is part

25



1
2 of Tab 45 of Exhibit 32B, all right, we will mark
3 that accordingly.

4
5 ---EXHIBIT NO. 32B, Tab 45: Two pages, January 13th
6 and January 14th.

7 THE COMMISSIONER: I guess everybody
8 will have to have a copy of that.

9 MS. CRONK: They do, sir, they have
10 been distributed.

11 THE COMMISSIONER: Oh, have they,
12 all right.

13 MS. CRONK: Q. Doctor, two final
14 points with respect to Janice Estrella. You mentioned
15 before the break your reaction and that of the
16 technicians in your biochemistry laboratory if some
17 indication was given to you that a particular sample
18 had been hemolyzed or was otherwise in question as
19 to its quality. Do you recall that?

20 A. Yes.

21 Q. What do you understand a
22 hemolyzed sample to be, Doctor?

23 A. One containing hemoglobin
24 from the red cells possibly due to red cell breakdown
25 during the collection of the sample, physiologically
or during the preparation of the serum sample from
the whole blood.



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Q. All right. And what effect if any would that have in your view on the quality of the sample for the purposes of a digoxin assay?

A. I think that that particular assay is relatively insensitive to hemolysis. We have analyzed quite a number of samples that were hemolyzed before and we have not obtained unexpected results directly associated with them.

Q. So, I take it then it is in respect of assays for other drugs, for example, potassium?

A. Yes.

Q. Drugs of that kind that a hemolyzed sample would be of concern?

A. Yes.

Q. All right. But it is not in your experience of concern with respect to digoxin assays?

A. No.

Q. All right. Doctor, as well, we have discussed what was in your mind, as I understand it, when you learned of the postmortem level on Janice Estrella of 72 nanograms?

A. Yes.

Q. What was in your mind as



1
2 possible explanations for that level and you have
3 told me first of the possible explanation that there
4 had been some error analytically in the assay or the
5 performance of the assay and you satisfied yourself
6 that that was not the case. Do I have that correctly?

7 A. Yes.

8 Q. All right. And you have told
9 me as well that it occurred to you that the sample
10 might have been taken too soon in time from the
11 time when the last dose of digoxin had been
administered and we have discussed that?

12 A. Yes.

13 Q. Was there in your mind at
14 the time, Doctor, any other possible explanation
15 for why this level of 72 nanograms might have
16 resulted in the case of Janice Estrella other than
those two explanations you have already offered?

17 A. Difficult as it may seem now,
18 no, there wasn't.

19 Q. Thank you, Doctor. Doctor,
20 we have heard from other witnesses that when they
21 learned of the level of 72 nanograms with respect
22 to that sample for Janice Estrella that amongst
23 other matters at least some of those individuals
24 assumed or thought that one possible explanation
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might have been a decimal error in the level that had been reported. Were you at the time satisfied that the mathematical calculations and the technical calculations that are performed on the gamma counter in the immunoassay test had been achieved correctly without error?

8

A. Yes.

9

Q. All right. Was that a matter which you specifically addressed at the time?

10

A. In relation to decimal point?

11

Q. Yes.

12

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A. No, in that the whole analysis had taken several days and everything was pointing to a higher result.

14

15

Q. Right.

16

A. So, there was no question that it was 7.2 as opposed to 72.

17

18

Q. All right. It was clear that the level was 72?

19

A. Yes.

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Q. Given that there had been, as we have seen, several dilutions of that sample before that result was achieved?

22

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A. That was my interpretation of these observations.

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Q. And is that your understanding
today of that level?

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A. Yes.

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Q. Thank you. Doctor, may we
turn then to the case of Kevin Pacsai. The evidence
with respect to that child has been that he died in
the Hospital for Sick Children on March 12th, 1981
and as well that a number of digoxin assays both
during his life and on a postmortem basis were
carried out in the biochemistry laboratories. Can
you tell me, Doctor, were those assays conducted
under your supervision?

13

A. Those assays for digoxin?

14

Q. On Kevin Pacsai.

15

A. For digoxin?

16

Q. Yes.

17

A. Yes.

18

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Q. All right. Would you turn,
Doctor, if you would please to Tab 45 again of
Exhibit 32B.

20

A. Yes.

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Q. It is Tab 45, Doctor, page 23
if you would please. I'm looking, Doctor, at the
entries for the results of digoxin assays conducted
on March 13, 1981 which are set out in the bottom



1
2 half of page 23. Do you see those entries?

3 A. Yes.

4 Q. All right. Doctor, I'm
5 referring to items numbered 4 and 5 amongst those
6 entries related to Kevin Pacsai and specifically
7 if I'm reading those entries correctly, and I
8 would ask you to tell me if I am not, it appears
9 that as a sample taken on March 12th, 1981 was
10 assigned Sample No. H88043, that it came from the
11 ICU and that it was assayed with the result of
12 greater than 10 nanograms. Do you see that initial
entry, Doctor?

13 A. Yes.

14 Q. All right. And immediately
15 below that, Doctor, there is another entry also
16 related to the same number taken on the same day
17 and then these words appear CMT, NSQ for further
dilution.

18 A. Yes.

19 Q. Could you tell me please
20 what those words refer to?

21 A. CMT is short for comment, it
22 indicates that the person who is to enter these
23 results into the laboratory computer should enter
24 in the location for comments. The following comment
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NSQ for further dilution.

Q. All right. I take it then that with respect to that particular sample after the first assay had been done there was no further sample, or at least insufficient sample available for further dilution and analysis, is that correct?

A. After the...

Q. After the first assay had been done there was then insufficient sample available for further dilutions and for further assays, is that correct?

A. Yes. In fact, there was very, very little of this sample available. You will note on the left hand side it says one tube and then it says one tube times two.

Q. All right.

A. So, there was 50 microlitres available to put into one tube and there was presumably 25 microlitres or a very little amount to put into the next tube. Otherwise, the technologist would have done everything in duplicate, which is the usual way.

Q. I see, Doctor. Doctor, referring to that first reference to one tube, immediately below that we see a number which appears



1
2 to be 16. It is either 160 or 116.0. Do you know
3 which it is?

4 A. It looks as though there is
5 a decimal point directly on the line, doesn't it.

6 Q. Do you know what that refers
7 to, Doctor?

8 A. Not unless the computer
9 printout - the computer will give a number even if
10 that number is greater than 4.7 or greater than top
11 standard. That number is unreliable and it is
12 produced by the computer, by an extrapolation
13 process. On occasion we will note the actual number
14 that was obtained by the computer printout on the
15 computer printout by the computer as an aside; in
16 other words, we would report a greater than 4.7,
17 let us say, but if the computer printout happened -
18 our own internal section printout said 5.3 or 5.4
19 we may note that somewhere in our book and perhaps
20 the computer produced the result of 16. Above the
21 high standard, this has relatively little reliability
22 and that we wouldn't report that number, but it is
23 useful internally to know how much higher than that
24 number it is. My guess would be that the 16 is a
25 number that is produced by the computer.

Q. All right. And in that



1
2 regard, Doctor, I take it that you would not be
3 satisfied that the actual level over 10 was 16?

4 A. No.

5 Q. That number is unreliable?

6 A. No.

7 Q. All right.

8 A. And in fact the over 10 which
9 appears to be associated with the first analysis is
10 in fact the result of the two analyses together.
11 That was the report that we produced on the basis of
12 those two analyses, the single tube and the times 2
tube.

13 Q. All right. Well, you are
14 anticipating me, Doctor, because I was going to
15 then ask you what the meaning of the entry on the
16 second reference to one tube was because we see
17 encircled the numbers times 2 and I took that to
18 mean that the sample when it originally arrived was
19 assayed neat and then was assayed times 2 and it
20 was a result of that dilution that the level of greater
than 10 was achieved. Do I have that correctly?

21 A. Yes, except that these were
22 done simultaneously.

23 Q. I see. So, it was in respect
24 of the second tube, it was the second tube of
25



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specimen that was diluted times 2.

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A. Second tube. I'm sorry, are you saying that there are two sample tubes coming in or are you talking about two analytical tubes?

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Q. I'm talking about two analytical tubes.

7

8

A. Okay.

9

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Q. The question probably to you, Doctor, is was this sample in part assayed neat and then in part assayed on a diluted basis of times 2?

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A. Yes.

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Q. All right. And was it as a result of that dilution assay that resulted in a level of greater than 10?

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A. Yes.

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Q. All right. And with respect to that level once again, Doctor, we see that the first and the second entry refer to the ICU. In light of what you have explained to us previously is the proper interpretation to be placed on information in that column, I take it that the request for the assay came to the biochemistry lab from the ICU. Do I have that correctly?

23

24

25

Well, to assist you, Doctor, and there is one other matter and then perhaps we can look at



1
2 the requisition form and that may assist you, all
3 right?

4 A. You are implying that the
5 patient was on the ICU when the sample was taken.

6 Q. No, I wasn't suggesting that.
7 As I understand it that is in fact the evidence
8 to date, but as I understand what you have said about
9 the information contained in that column, when you
10 insert a ward, a specific ward, in this case the ICU,
11 that means that they were the originator of the
request for the assay?

12 A. Under normal circumstances, yes.

13 Q. All right.

14 A. But in fact this wasn't the
15 case with this particular sample.
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Q. All right. And where did
you understand the request came from?

A. Well, my understanding
that came to some extent later was that Dr. Costigan
himself had brought the sample.

Q. And do you know where
the child was when he drew that sample?

A. Where the child was? I
believe the child was in the ICU at the time.

Q. Thank you, doctor.

And, doctor, under the time
column of information you see the number 2100 hours.
Now in accordance with your evidence as to how the
information in that column is normally to be
interpreted, one would usually take that to mean
that the sample was collected at 2100 hours on the
12th of March. That would be the interpretation in
accordance with the normal rules; is that correct?

A. If this were a normal
sample, yes.

Q. Was there something about
this sample of and in itself that was unusual,
doctor?

A. Yes. Firstly I don't
know whether that 2100 hours -- I believe that 2100



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hours has been put in later because there is a vertical dash down which suggests that we didn't know the time at the time we were doing the analysis on the 13th of March.

It is also my understanding that this particular sample was a very unusual sample. As I mentioned, Dr. Costigan, it is my understanding, brought it in, and that this sample had spent some time in Hematology.

Q. And would that somehow influence the entry at the time in the book, doctor?

A. Yes, because I think on the basis of the information that we had right at the instance of doing the analysis we didn't have that particular specimen time noted.

Q. Right. To assist you in that regard, doctor, the clinical chemistry requisition form which applies to this sample, found at Tab 55 of the same book that you are looking at, indicates that the sample was taken on March 12th, and no time, or at least no hours indicated as to when the sample was taken.

Would you turn to Tab 55, please.

A. Yes.

Q. Do you have it?



Ellis
dr.ex. (Cronk)

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A. Yes.

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Q. There is, however, a

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date stamped there that appears upside down, at

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least on my copy, and it is March 12, 1944 hours.

6

Do you see that?

7

A. Yes.

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Q. Am I correct, doctor,

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that the date stamp of that kind when it appears on

10

these requisition forms is a date stamp attached

11

or affixed to the requisition forms once the form

12

is received in the Biochemistry Department?

13

A. It is printed, yes, by

14

a time clock.

15

Q. And the purpose of doing

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that is to indicate when the sample is received in

17

Biochemistry?

18

A. Yes.

19

Q. So in this case it would

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appear that the sample was received on March 12

21

at 7:44 p.m.

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A. That is correct.

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Q. All right, doctor.

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Doctor, as you indicated it was

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your understanding that the sample had been obtained
by Dr. Costigan, as I understood it, while the child



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was in the ICU. That is when the sample had been obtained.

When this assay was being conducted on March 13th, did you have any understanding then as to whether the sample was an ante mortem or post mortem sample?

A. On the 13th of March?

Q. Yes.

A. I had no reason to believe this was a post mortem sample.

Q. Did you assume that it was an ante mortem sample?

A. Dr. Costigan was I think in the lab or communicated to the lab -- we just couldn't quite explain how a sample that had been received on this particular day -- I think the time of receipt in the Biochemistry Lab follows the time of the child's death.

Q. That is correct, doctor.

A. So we really couldn't explain whether this was really a post mortem or an ante mortem sample.

Q.. At the time?

A. At the time, yes.

Q. Doctor, do you recall how



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this sample arrived in the Biochemistry Lab?

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A. I personally don't recall

how it arrived, but we tried to piece together

information afterwards and spoke to various people,

and it is my understanding, as I say, that Dr.

Costigan was concerned when the child died, whenever

the child died; he was concerned that the child had

died and he attempted to, because of the clinical

condition of the patient and the symptoms that the

child was showing before death, he became concerned

about the possibility of digoxin toxicity, so that

he had or he had instituted the taking of several

blood samples.

If my recollection is correct

or if my understanding of the evidence is correct he

had initiated the taking of several blood samples,

one of which I think was for hematology requests,

and the other which was for electrolytes at the

time the child was ill in the Intensive Care Unit.

It is our policy in Biochemistry

to discard any sample remaining at the end of the

shift, at the end of the technology shift, for

routine tests.

In other words, if something

comes in for potassium or something comes in for



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gases, any leftover sample will be discarded unless something else has been requested that hasn't been analyzed. Okay.

So I think when he then thought about digoxin toxicity he tried to look out the sample that he had sent to Biochemistry, if my understanding is correct, but wasn't successful because the sample that we had had had been thrown away.

Q. May I stop you there for a moment, doctor.

A. Yes.

Q. To the best of your understanding was the sample that was actually assayed that resulted in this level for digoxin brought to the lab by Dr. Costigan?

A. Yes.

Q. Doctor, to assist you with respect to the events of how that sample arrived in Biochemistry and the events following the assay, it is my understanding the technologist involved in the conduct of the assay kept notes of those events.

A. No, she pieced together notes fairly shortly after the further deaths.



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Q. I am showing to you,
doctor, handwritten notes dated around March 24,
1981. It is indicated that they are "Mary's notes".

Can you identify those notes for
me and, if so, who is the author of them?

A. Yes. It is my recollection
that these notes were prepared by Mary Allin,
A-l-l-i-n.

Q. I'm sorry, Mary Allin?

A. Allin, yes.

Q. And who is Mary Allin?

A. She was one of the
technologists.

Q. In your lab?

A. In my lab.

Q. All right. Was she
involved in the conduct of this assay on this sample
of Kevin Pacsai?

A. No, she wasn't in
respect of this particular one.

Q. All right.

I would ask, sir, that those
notes be marked as the next exhibit.

THE COMMISSIONER: Yes, I guess
so.



Ellis
dr.ex. (Cronk)

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MS. CRONK: Q. Doctor, I take
it these notes were brought to you by Miss Allin?

A. Yes.

Q. All right. Do you
recognize her handwriting?

A. I believe it to be hers.

THE COMMISSIONER: What number?

THE REGISTRAR: 209.

--- EXHIBIT NO. 209: 2-page document entitled
"Mary's Notes, around 24
March '81".

MS. CRONK: Q. Doctor, with
reference to the first paragraph of the note, it
reads:

"Peter came into the lab to
query a digoxin level on..."

THE COMMISSIONER: Just a moment,
please.

MR. ROLAND: Mr. Commissioner,
I haven't objected to the introduction of the notes,
but I take it it is clear these are not contemporaneous
notes.

THE COMMISSIONER: No.

MR. ROLAND: By Mary Allin after
the event.

THE COMMISSIONER: Even if they



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were contemporaneous they wouldn't be admissible in any proper court of law which this is not.

MR. ROLAND: Exactly. The purpose, of course, and the use of contemporaneous notes is for a witness to refresh -- if there is some accurate value to the witness because they were made contemporaneous with the event and the witness refreshes his memory.

THE COMMISSIONER: That would be of assistance to him but the only reason we can accept them is because we are a Commission.

MR. ROLAND: Exactly.

THE COMMISSIONER: We are not a court and we can receive anything. Even if it comes in by carrier pigeon or something we can take it for what it is worth.

MR. ROLAND: That may very well happen in this inquiry.

THE COMMISSIONER: Yes.

MR. ROLAND: All I want to say is that because they are not made contemporaneous to the event they should be regarded as far as accuracy is concerned with that in mind.

THE COMMISSIONER: Yes. I agree with everything you have said but still you are



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EE10

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not objecting and I guess by our rules they are
clearly admissible.

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All right.

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Q Doctor, with respect to the first paragraph of the notes as I understand the entry it reads as follows:

"Friday morning. Peter came into the lab to query a digoxin level on Kevin Pacsai. Apparently the blood arrived Thursday evening yet the baby had died Thursday morning. I looked up the requisition, the serum (hemolyzed) was separated and frozen and requested for digoxin only. There was no sample time on the requisition. Peter explained that there was a query over ... "

I take that to be potassium?

A. Yes, K-plus.

Q " ... or digoxin toxicity. So on setting up ...

The digoxins?

A. Yes.

Q " ... the serum was done straight and on a X2 dilution, anticipating possible high digoxin. The result was greater than 10 on X2 dilution but we figured the sample



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"must have been taken shortly after
the digoxin had been given to the
patient as we didn't have dose and
sample times."

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Stopping there for a moment, Doctor,
I take it you have seen these notes before?

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A. Yes.

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Q. Did Mary Allin at any point
describe to you the events of the Thursday evening?
That is the arrival of the sample and the Biochemistry
lab for assay?

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A. She would not have been present.

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Q. All right. Do you know who
Miss Allin is referring to as Peter?

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A. That would be Peter Huggard.

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Q. All right.

A. Huggard, H-u-g-g-a-r-d.

Q. And what is his position, Doctor?

A. His position is chief

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technologist.

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Q. In the Biochemistry lab?

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A. Yes.

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Q. And with respect to this
particular sample, Doctor, was it suggested to you
following the conduct of the assay on the sample by



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any of the involved technologists that the sample may have been taken shortly after the digoxin had been given to the patient?

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A. No, I don't think so. In fact on that requisition I believe Dr. Costigan wrote "dig. toxicity question mark" if my recollection of the requisition is correct.

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Q. Thank you. Apart from whatever Dr. Costigan wrote on the requisition form, do you have any recollection of the technologists who were involved in performing the assay raising with you the suggestion that the greater than 10 level might be explained by virtue of the fact or the suggestion that the sample had been taken in close proximity to the time at which the last digoxin dose had been given.

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A. Just taking the results as they stood that was one possibility.

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Q. Do you recall whether or not that was specifically raised with you by the technologist who conducted the assay?

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A. I think we later - I think we learned the following week, early in the following week that the last sample, the last digoxin dose had been given the previous night, prior to taking the blood sample.



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Q. Well, Doctor, I would like to direct your attention to March 13th, the day this assay was conducted as opposed to anything that may have happened the following week.

On that day when the assay was conducted do you recall one way or another whether or not, first of all, the level of greater than 10 was brought to your attention? Were you made aware of that on the 13th of March?

A. Yes, I think I was, yes.

Q. And when you were made aware of that level did any of the technologists who had been involved in performing the assay as best you can now recall it suggest to you or raise with you a possible explanation for that level, mainly that the sample had been taken too soon after the last dose of digoxin had been given?

Was that a matter discussed on March 13th as best you can recall?

A. This is something that we always consider because--as our first explanation for something unless there is a positive indication to the contrary.

Q. All right.

A. Because over the course of the previous few years that had been the most common reason



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why we had got unusual digoxin results. You know, you go down to the ICU and you find out that the sample, they have got a new nurse on and the nurse didn't really know the procedure. She remembered that she should take a digoxin sample - not in respect of this case but I am saying in the general case you usually find that somebody wasn't quite sure and they took a digoxin result at the inappropriate time, one hour, two hours, half an hour after getting the dose.

Q. So I take it then, Doctor, that given your general experience in the past with digoxin assay results that appeared to be elevated or irregular, the possibility of that happening was something that would have been in your mind on the 13th of March?

A. Very much so, yes.

Q. And, Doctor, given that Miss Allin's notes indicate that the sample at issue resulted in a level greater than 10 on a dilution times two, I take it you would have no difficulty in accepting that her notes refer to the sample numbered H88043 that we have been discussing in the digoxin book?

A. Yes.

Q. And if we could turn then to the



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second passage of the notes:

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"Monday morning. First thing

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(before 8:30 probably) phone call

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requesting Friday's digoxin results

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on Kevin Pacsai."

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A. Yes.

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Q. "I explained that there was a

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query about this sample and I asked

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if he knew about this. He said yes

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he knew all about it, that he had

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brought the sample to the lab himself

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Thursday evening - that he had dug

it up from ... "

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I take it Haematology?

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A. Yes.

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Q. "I asked what time sample drawn.

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He said Thursday morning. I asked

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when the patient had received his

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last dose before the sample was drawn.

He said 9.00 p.m. Wednesday evening."

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Going to the next page:

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"I was surprised. I explained: well

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the dig. result was high, greater

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than 10 on dilution so it looks like

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dig. toxicity. We didn't have enough

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"serum to do a greater dilution.

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A. I personally don't, no.

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Q. Do you have any understanding or knowledge as to who the person was who made the phone call that Miss Allin is referring to in this portion of her notes?

A. Discussing it later on the following week I believe this person is Dr. Costigan.

Q. All right. I take it then, Doctor, perhaps you are in a position to tell me did Miss Allin draw to your attention the nature of the discussion that she had had with Dr. Costigan concerning the timing of the last dose of digoxin and the timing at which the sample was drawn? Was that a matter that you discussed after the 13th of March with Miss Allin?

A. I am not quite sure with



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Miss Allin particularly, but also with the doctors who were concerned, who were involved, with Dr. Costigan particularly.

Q. Did you speak to Dr. Costigan personally about that?

A. Well, all aspects of this, yes. He was concerned about the case and so there were various conversations that took place.

Q. All right. Doctor, you have told me you don't recall specifically whether or not Miss Allin passed along a phone call to you?

A. No.

Q. And Dr. Costigan on Monday, March 16th?

A. No.

Q. Do you recall one way or another?

A. I don't, no, but I have seen these notes several times since that time.

Q. Do you have any reason to disagree with the notes?

A. Oh, no, no. I think it could well have happened. I just don't remember every single phone call that I make.

Q. I understand.

Then with respect to the discussion



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concerning the time at which the sample had been
obtained, was there in your mind on March 16th any
further issues as to whether or not that sample had
been drawn at an inappropriate time?

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A. I am sorry, on March 16th?

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Q. On Monday, March 16th, was there
any further issue in your mind as to whether that
sample had been drawn at an inappropriate time?

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A. This particular sample was not
of too much concern to us in that we had additional
materials that we hadn't yet analyzed, okay, so there
were some samples dated 13th of March, autopsy samples
that were actually analyzed the following Monday,
March 16th. And so we are dealing there with a result
in front of us but also some unknown question marks
behind it. You know, some samples had already arrived.

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Q. I will be coming to the post-
mortem samples in a moment, Doctor.

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A. Okay.

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Q. But just dealing with this
sample that Dr. Costigan apparently brought to the
Biochemistry laboratory on the evening, on Wednesday
evening, you have told us that because of your
general and prior experience with respect to digoxin
assays --



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A. Was it Thursday evening or
Wednesday?

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Q. Wednesday evening according to
the notes. Oh, I am sorry. It was Thursday evening,
it was the last dose that was given on Wednesday. You
are quite right, Doctor, I am sorry.

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You have told us because of your prior
experience with digoxin assays the possibility of an
erroneous level resulting because a sample was taken
too soon after the last dose was a matter that was
very much in your mind on March 13th?

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A. Yes.

Q. All right. Do I understand
that correctly?

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A. Yes.

Q. So that was I take it an
unresolved issue in your mind at that time with respect
to the sample?

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A. Yes.

Q. That was a possible explanation
for the sample?

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A. Yes.

Q. Then comes the Monday, March
16th. My question of you, Doctor, is by that time, on
the 16th of March, did you then have any further or



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lingering question in your mind as to whether or not
this particular sample had been drawn at an
inappropriate time?

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A. No. Well, I had no reason to
believe that it had been drawn at an inappropriate time.

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Q. Well, on the basis of your
discussions with Dr. Costigan do you recall discussing
personally with him the time at which the last dose
of digoxin had been administered and the time at which
the sample had been taken?

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A. We came to know that at some
time during that week.

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Q. And when --

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A. I suspect - you know, it could
have been the Friday; it could have been the Monday.
I think it was probably the Monday.

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Q. And, Doctor, when you did come
to know that, would I be correct then in understanding
your evidence to be that you would no longer regard
that possibility as a likely explanation for this
level?

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A. Yes.

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Q. Doctor, on page 2 of Miss
Allin's notes we see reference to a haemotology sample
containing EDTA. Can you tell us what that refers to?

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A. This is ethylene diamine tetra-acetic acid and it is used as a preservative for haematology samples.

Q. Do you recall discussing with Dr. Costigan the possible implications of EDTA being contained in a blood sample used for digoxin assay?

A. If a sample is unusual in respect to the usual method of preservation, then we would obviously be concerned about that.

Q. I am sorry, Doctor, that really wasn't my question. My question was do you recall discussing with Dr. Costigan the possible implications of EDTA being contained in a blood specimen sent for digoxin assay?

A. Not with him specifically on that particular date.

Q. Do you recall that issue being raised?

A. Yes.

Q. In the context of this sample on Kevin Pacsai?

A. Yes. Right.

Q. And as a result of that issue being raised --

A. Sorry. I recall it being raised



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because - well, I recall this question coming up, and
in fact on March 17th that we did various things in
EDTA to see whether it made any difference.

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Q Well, that was my next question of you, Doctor. Can we turn if you would to page 25 of Tab 45, Exhibit 32B, do you have that?

A Yes.

Q Doctor, I take it you just told me that on March the 17th you did run tests to look into this issue of the possible effect of EDTA?

A Yes, very preliminary kind of tests.

Q Before you ran those tests, I ask you to address your mind to the situation before you ran those tests. Did you then have any opinion based on your experience as to whether EDTA contained in a blood specimen could result in an artificial or an unreliable digoxin level?

A I would not have thought it likely that EDTA would have interfered with this particular assay, but I couldn't exclude the possibility that it might prior to doing these couple of experiments.

Q And Doctor, what then did you do on March 17th to explore the matter further?

A On March 17th basically we took a controlled specimen and we put it into an EDTA tube and we analyzed it, and this is No. 19 down the left-hand side of the page on March the 17th.



FF.2

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Q. Control A - EDTA?

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A. Control A - EDTA, 1.1. Control A

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in that particular run had been 1.3, Item 1 on the

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top of that particular page.

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Q. So that the discrepancy between

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the normal control used on the assay and the

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controlled EDTA sample was a variation only of the

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difference between 1.1 and 1.3?

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A. Yes, our control had not gone

above 10 or 8 or 5.

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THE COMMISSIONER: I am sorry, I

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haven't seen this yet. I see at the bottom March 17th,

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there is Control A and EDTA A?

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THE WITNESS: Yes.

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THE COMMISSIONER: And there is

something K?

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THE WITNESS: This is Item 19, Tube 19.

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THE COMMISSIONER: Yes.

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THE WITNESS: If you look right back

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to the beginning, Control A, Item 1.

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THE COMMISSIONER: Yes, 1.3 and 1.1.

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THE WITNESS: Yes.

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MS. CRONK: Q. I take it then, Doctor,
the only differential was .2?

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A. Yes.

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Q. Between the readings on those two samples?

A. Yes. In addition there is a patient sample, Item No. 7, Allard, K., 0.8.

THE COMMISSIONER: Oh, yes.

THE WITNESS: Item No. 7, but Item No. 18, Allard, K., EDTA 0.7.

MS. CRONK: Q. So the discrepancy in that case was .1?

A. Yes, on the basis of these two samples we assumed there would not be a difference.

Q. Was it your conclusion on the basis of those two samples that EDTA would not result in an irregular or false digoxin level reading?

A. Yes.

Q. Doctor, just in summation, and I am conscious of the time, Mr. Commissioner.

MR. COMMISSIONER: No, no.

MS. CRONK: Q. I take it, as at March 17th you had ruled out as a possible explanation for the level of greater than 10 the possibility that the sample itself had been taken too close in time to the time of the last digoxin administration, that had been ruled out, is that correct?

A. I think that was the case, yes.



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(Cronk)

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Q And you had also by virtue of the tests run by you on March 17th, ruled out, or at least eliminated the possibility that the EDTA present in the sample could have resulted in an irregular or unreliable level, do I have that correctly?

A. Could result in gross differences whereby a very low value or a normal value becomes greater than 10.

Q You have ruled out the possibility that the EDTA could have resulted in a falsely elevated level?

A. To our reasonable satisfaction, yes.

Q All right. But in addition to that by March the 17th we also received some autopsy samples and analyzed them on the same patient, and these samples had not been collected in EDTA. So whether EDTA interfered or not was less relevant, you know, after March 17th?

A. I see, Doctor, thank you. Other than those two possible explanations, or those two factors which you took into consideration, was there then, dealing strictly with this sample that came from Dr. Costigan, was there then anything else that presented itself to your mind as a possible explanation



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for this level of greater than 10?

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A. No, because in conversations that took place at or around this time - well, each sample requisition had queried dig. toxicity. Also I think Dr. Costigan had mentioned that in his opinion this child should not have died.

Now, whether that occurred on the Monday, Tuesday or Wednesday I don't know, some time during this week that in his opinion this child should not have died.

Q. Doctor, in addition to any discussion or any expression of opinion that Dr. Costigan might have made with respect to the child's death, did you on March 17th, have any remaining concern as to the validity of this level?

A. No, not on March 17th.

Q. Thank you, Doctor. May we rest there for the evening, sir?

THE COMMISSIONER: Yes, until 10 o'clock tomorrow morning then.

--- Whereupon the Hearing was adjourned at 4:40 until Thursday, October 13th, 1983, at 10:00 a.m.

